

# PATIENT MONITOR

## PM PRO-4

MANUAL BOOK

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# Chapter 1 Intended Use and Safety Guidance

## 1.1 Intended Purpose

The patient monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.

## 1.2 Intended Population

The patient monitor is applicable to adult, pediatric, and neonatal usage in hospital environments.

## 1.3 Intended User

Users of the patient monitor must be trained and experienced medical professionals.

## 1.4 Intended Use/Indications for Use

The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood ( $\text{SpO}_2$ ), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide ( $\text{CO}_2$ ), and cardiac output (C.O.).

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are not intended for MRI environments.

The cardiac output (C.O.) is only intended for adult patients.

## 1.5 Contraindication

Unknown.

## 1.6 Safety Guidance

Federal (U.S.) law restricts this device from being sold by or on the order of a physician.

### **WARNING**

- 1 Medical technical equipment such as these monitor/monitoring systems must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
- 2 Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Intended Use". Strictly observe all WARNING and PRECAUTION statements throughout these instructions for use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.
- 3 Do not use any monitoring system, sensor, cable, connector, or screen that appears damaged. Remove any damaged equipment from service for inspection by a qualified service technician.

**WARNING**

- 4 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- 5 SHOCK HAZARD-To avoid the risk of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
- 6 Do not come into contact with the patient, table, or the monitor during defibrillation.
- 7 The simultaneous use of a cardiac pacemaker or other electrical stimulators may cause safety hazard.
- 8 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
- 9 Devices connecting with monitor should be equipotential.
- 10 Extreme care must be exercised when applying medical electrical equipment.  
Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.
- 11 Route all cables carefully to avoid possible entanglement, strangulation, or electrical interference.
- 12 If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.
- 13 Do not rely exclusively on the auditory alarm system for patient monitoring.  
Adjustment of alarm volume to a low level or OFF during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
- 14 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore, anybody who connects additional equipment to the signal input or output connector to configure a medical system must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
- 15 The monitor is equipped with wireless AP/Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.
- 16 The monitors are not intended for use in an MRI environment.

**WARNING**

- 17 Only patient cable and other accessories supplied by the manufacturer can be used. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.
- 18 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
- 19 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents; otherwise, it may cause shock hazard. Consult your service personnel.
- 20 Keep away from fire immediately when leakage or foul odor is detected.
- 21 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test before installation and any time new medical equipment is added to the Wireless LAN coverage area.
- 22 Clinical decision making based on the output of the device is left to the discretion of the provider. The equipment should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptom. If uncertain about the accuracy of any measurement, first check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.
- 23 This equipment is not intended for home use.
- 24 Do not perform service or maintenance on the device or any accessory while it is in use.
- 25 The appliance coupler or mains plug is used as an isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.
- 26 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
- 27 Only recommended batteries shall be used for the monitor.
- 28 Additional multiple socket-outlets or extension cords cannot be connected to the system.
- 29 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.
- 30 Connecting any accessory or other device (such as the computer) to this monitor makes the monitor and connected devices a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
- a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
  - b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
- 31 All the accessories connected to system must be installed outside the patient vicinity if they do not meet the requirement of IEC/EN 60601-1.

**WARNING**

- 32 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
- 33 Portable and mobile RF communications equipment can affect medical electrical equipment. See the recommended separation distances provided in this user manual.
- 34 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.
- 35 The monitor should not be used adjacent to or stacked with other equipment.  
If adjacent or stacked use is necessary, the monitor shall be observed to verify normal operation in the configuration in which it will be used.
- 36 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously. Such parts include a USB connector, VGA connector or other signal input/output connectors.
- 37 Make sure networking function is used in a secure network environment.
- 38 SHOCK HAZARD - Do not connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
- 39 SHOCK HAZARD - Do not connect electrical equipment that were supplied as a part of the system directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
- 40 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.
- 41 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only accessories approved by the manufacturer.
- 42 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
- 43 To protect the monitor from damage during defibrillation, to use for accurate measurement information, and to protect against noise and other interference, use only accessories specified by the manufacturer.
- 44 No modification of this equipment is allowed without authorization of the manufacturer.
- 45 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 46 The monitor is suitable for use in the presence of electro surgery. When the monitor is used with HF surgical equipment, the user (doctor or nurse) should be cautious about patient safety.
- 47 Do not touch the system components. Otherwise patient injury may result.

**WARNING**

- 48 If the accessory is accidentally disconnected, it shall be reconnected by a trained healthcare professional.
- 49 Always remove non-defibrillation-proof accessories during defibrillation.

**PRECAUTION**

- 1 The packaging is to be disposed of according to local or institutional regulations in order to avoid environmental contamination. Store the packaging out of reach of children.
- 2 The device and accessories are to be disposed of according to local regulations. Alternatively, it can be returned to the dealer or the manufacturer for recycling or proper disposal.
- 3 Batteries are hazardous waste. Do NOT dispose it together with the household garbage. At the end of their life, hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office or the shop where you purchased the product.
- 4 Some settings are password protected. Password should only be changed by authorized personnel. Contact the relevant personnel of the medical institution for password to these features.
- 5 Ensure that the monitor is supplied with continuous electric power during operation from the main source power or batteries. Sudden power failure may cause failure to monitor parameters.
- 6 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, and so forth.
- 7 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dusty areas, high temperatures and humid environments.
- 8 Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.
- 9 The Ingress Protection of the monitor is IPX1. Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings, since this may cause damage to the monitor. If liquid gets on or in the monitor, please contact the service personnel of the manufacturer.
- 10 To ensure patient safety, use only parts and accessories manufactured or recommended by the manufacturer.
- 11 Do not touch the touch screen with a sharp object.
- 12 Before connecting the monitor to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the device label or in this user manual.
- 13 Protect the device against mechanical damage resulting from falls, impacts, and vibration.

## PRECAUTION

- 14 The device must be connected to the ground to avoid signal interferences.
- 15 Poor contact might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it as needed.
- 16 To protect eyes from damage, do not look directly into barcode scanner's light for long periods of time.

**NOTE:**

- 1 In case of power interruption, if the power is restored, monitoring will resume with all active settings unchanged.
- 2 Position the device in a location where the operator can easily see the screen and access the operating controls.
- 3 The monitor can only be used on one patient at a time.
- 4 The pictures and interfaces in this manual are for reference only.
- 5 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.
- 6 When there is measurement beyond range, an invalid measurement or no measurement value, a -?- will be displayed.
- 7 In normal use, the operator shall stand in front of the monitor.

### 1.7 Symbols

|   |  |   |
|---|--|---|
| 1 |  | DEFIBRILLATION-PROOF TYPE CF APPLIED PART                             |
| 2 |  | Caution   |
| 3 |  | MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment |
| 4 |  | Equipotentiality  |
| 5 |  | Alternating Current   |
| 6 |  | Battery check   |
| 7 |  | Power-on indication   |

|    |  |   |
|----|--|---|
| 8  |  | Power Supply switch                                 |
| 9  |  | Serial Number                                       |
| 10 |  | Network port  |
| 11 |  | USB (Universal Serial Bus) Connection               |
| 12 |  | Temporarily/permanently silence audible alarms      |
| 13 |  | NIBP measurement                                    |
| 14 |  | Alarm reset   |
| 15 |  | Menu  |
| 16 |  | Video output  |
| 17 |  | Nurse call port                                     |
| 18 |  | Output  |
| 19 |  | CE marking  |
| 20 |  | Authorized representative in the European Community |
| 21 |  | Date of manufacture                                 |
| 22 |  | Manufacturer  |

|    |   |  |
|----|---|--|
| 23 | P/N   | Part Number  |
| 24 |    | General symbol for recovery/recyclable   |
| 25 |    | The products marked with this symbol apply to the European WEEE directive. This symbol indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment. |
| 26 |    | Operating instructions   |
| 27 |    | See instruction manual/booklet<br>(Background: Blue; Symbol: White)  |
| 28 |  | Warning<br>(Background: Yellow; Symbol & outline: black)   |
| 29 |  | Gas inlet  |
| 30 |  | Gas outlet (evac)  |
| 31 |  | Ingress Protection IPX1 (Protected against vertically falling water drops)   |
| 32 |  | Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.   |
| 33 |  | Non-ionizing electromagnetic radiation   |
| 34 | Contains FCC ID   | Federal Communications Commission:<br>Contains FCC ID: SMQ9113EDAN   |
| 35 |  | DO NOT RE-USE  |

|    |  |                           |
|----|--|---------------------------|
| 36 |  | This way up               |
| 37 |  | Fragile, handle with care |
| 38 |  | Keep dry                  |
| 39 |  | Stacking limit by number  |
| 40 |  | Handle with care          |
| 41 |  | Do not step on            |
| 42 |  | Use-by date               |
| 43 |  | Medical Device            |
| 44 |  | Unique Device Identifier  |
| 45 |  | Protective earth (ground) |

NOTE: The user manual is printed in black and white.

## Chapter 2 Installation

### WARNING

The installation, including a correct protective earth connection, must only be carried out by qualified service personnel.

### PRECAUTION

A ventilated environment is required for monitor installation. Do not block the ventilation grille at the back of the device.

NOTE:

The monitor settings must be configured by the authorized hospital personnel.

### 2.1 Initial Inspection

Before unpacking, check the packaging and check that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the monitor and accessories. Check that all correct options and accessories are included.

If you have any question, please contact your local supplier.

### 2.2 Mounting the Monitor

Place the monitor on a flat, level surface, hang it on the bed rail, on a rolling stand, or mount it on a wall. For detailed information about how to install the mount adapter, see the *WallMounting Bracket Assembly Instruction*.

### WARNING

- 1 The wall mounting bracket can be fixed only on a concrete wall. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.
- 2 The safe loads of the wall mounting bracket and the rolling stand are 7.5 kg and 7.7 kg respectively. Exceeding the safe load may cause bracket to fail and the device to fall.

NOTE: Introduce regular checks of the mounting integrity depending on the local environment.

## 2.3 Connecting the Power Cord

1. Make sure the AC power supply complies with the following specifications: 100 V-240 V~, 50 Hz/60 Hz.
2. Connect the power cord provided with the monitor to the power input of the monitor. Connect the other end of the power cord to a grounded 3-pin power output.

NOTE:

- 1 Connect the power cord to the socket specialized for hospital use.
- 2 Only use the power cord recommended by the manufacturer.

## 2.4 Checking the Monitor

Make sure there is no damage to the accessories and cables. Turn on the monitor and verify that the monitor starts normally. Make sure all alarm lamps light up and the alarm sound is heard when turning on the monitor. See *Chapter Testing Alarms*.

### WARNING

Do not use the device if any damage is detected or if the monitor displays error messages. Contact the hospital technical personnel or the Service Representative immediately.

NOTE:

- 1 Check that all monitor functions are operating correctly.
- 2 If rechargeable batteries are provided, charge them each time before using the device to ensure adequate power.
- 3 After an extended period of continuous use, restart the monitor to ensure the steady performance and prolong the lifespan of monitor and battery.

## 2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder's door to check if paper is properly installed in the slot. If no paper exists, see *Chapter Recording* for details.

## 2.6 Setting Date and Time

To set the date and time:

1. Select Menu > System > System Time.
2. Adjust the Time Zone, Date Format, Clock Format and Display Seconds as desired.
3. Set the correct time of year, month, day, hour, min and sec.

Select Nighttime from and Nighttime to to define the beginning and end of Nighttime in ECG summary and NIBP summary.

To synchronize the system time with the server, set Time Synchronization to ON and configure the NTP server address or domain.

NOTE:

- 1 After the monitor is connected with the MFM-CMS, the system time shall not be changed.
- 2 After a prolong duration of the device out service, the system time setting may need to be readjusted.
- 3 If the system time cannot be saved and reverts back to the default value after restart, contact the service department of the manufacturer.
- 4 The default clock format is 24 hours. Select AM or PM as needed when Clock Format is set to 12 Hours.

## 2.7 Handing Over the Monitor

The users must be adequately trained to use the monitor before monitoring a patient.

To achieve this, the users should be provided with the following materials:

- Operational Manual – for full operating instructions.
- Quick Guide – for quick reminders during use.

## 2.8 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

NOTE: “Harmful interference” is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio

communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

## 2.9 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

## Chapter 3 Basic Operation

This manual is intended for healthcare providers using the PM PRO 4. Unless otherwise specified, the information here is valid for all the above products.

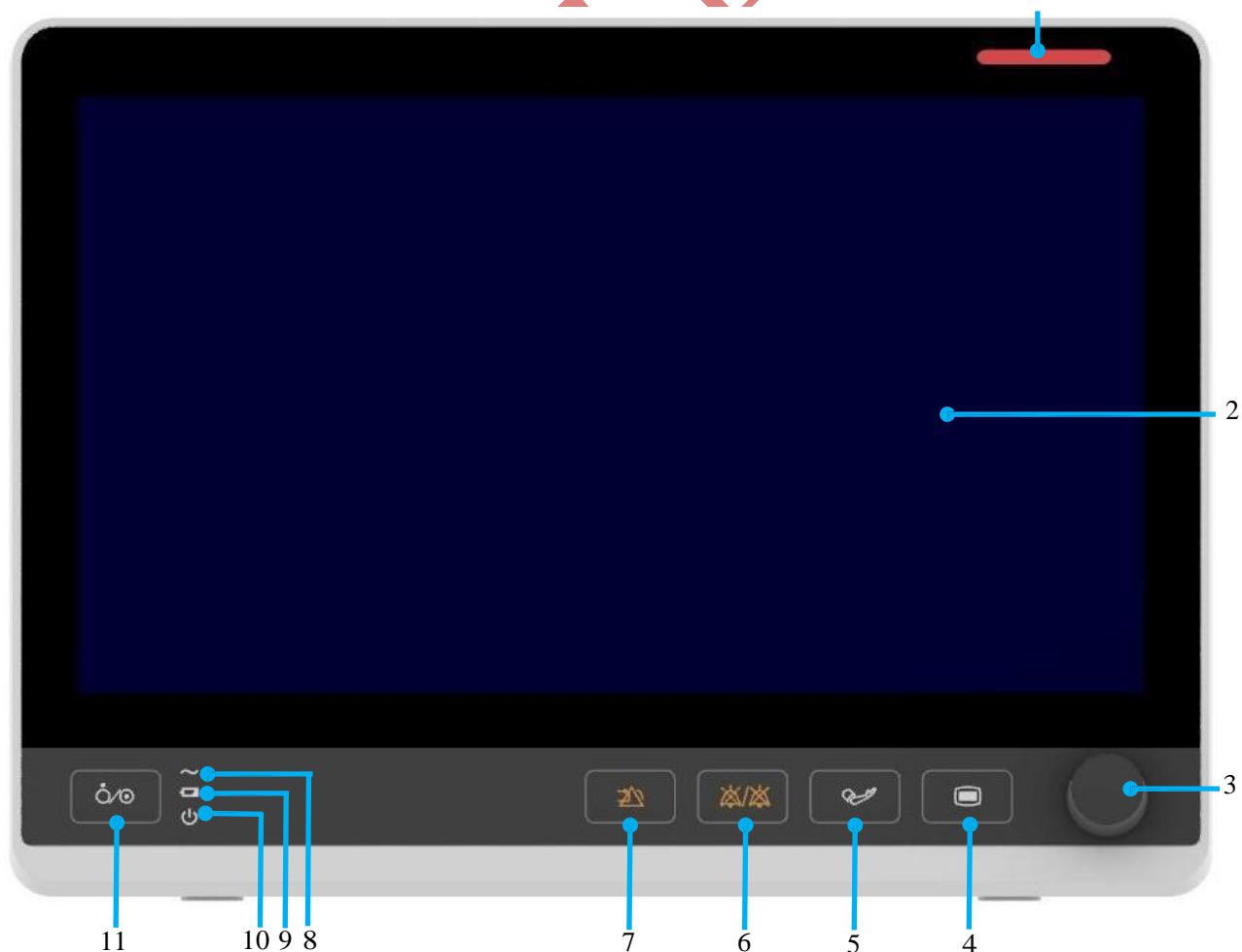
This user manual describes all features and options. Your monitor may not have all of them; they are not all available in all geographies. Your monitor is highly configurable. What you see on the screen, how the menus appear and so forth, depend on the way it has been tailored for your hospital and may not be exactly as shown here.

You may frequently use the following functions:

- ◆ ECG monitoring (See *Monitoring ECG* for more information.)
- ◆ SpO<sub>2</sub> monitoring (See *Monitoring SpO<sub>2</sub>* for more information.)
- ◆ PR monitoring (See *Monitoring PR* for more information.)
- ◆ NIBP monitoring (See *Monitoring NIBP* for more information.)
- ◆ Alarm (See *Alarms* for more information.)

### 3.1 System Components

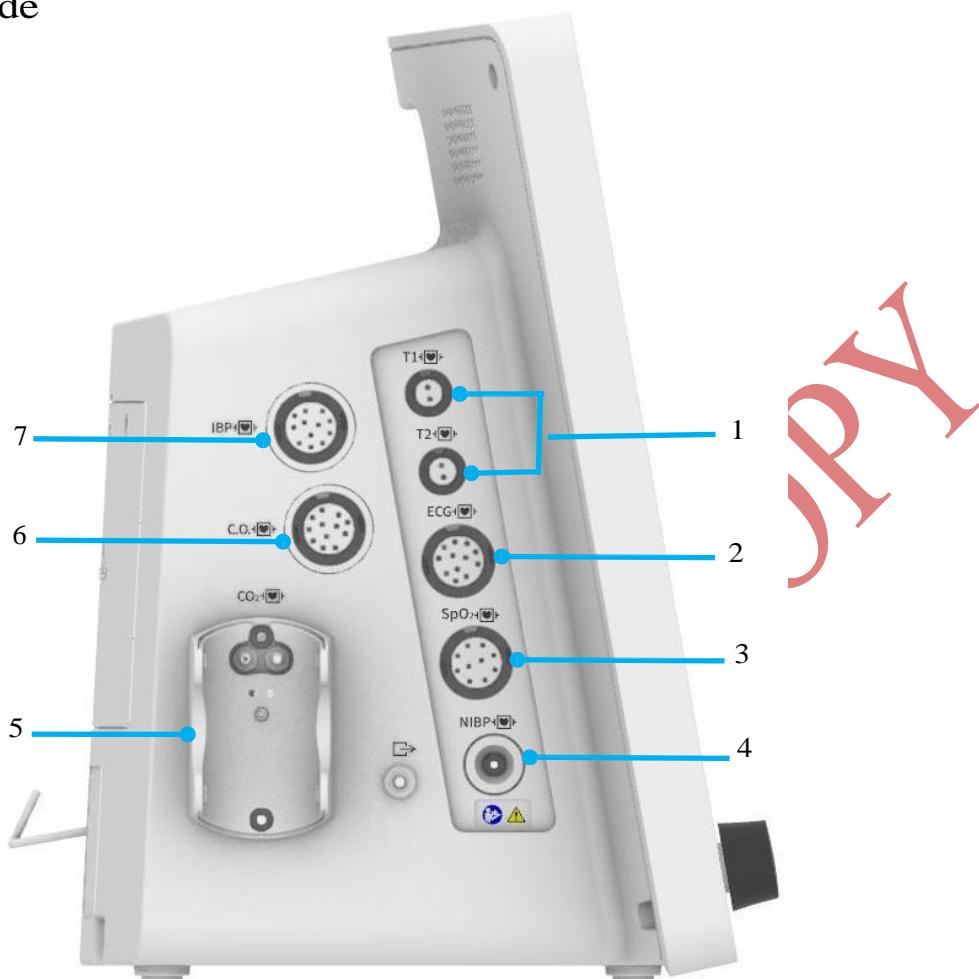
#### 3.1.1 Front View



|    |  |
|----|--|
| 1  | Alarm indicator:<br>When a physiological alarm or technical alarm occurs, the indicator lights and flashes based on the alarm priority: <ul style="list-style-type: none"><li>• High-level alarm: flashes RED</li><li>• Medium-level alarm: flashes YELLOW</li><li>• Low-level alarm: constantly CYAN.</li></ul> |
| 2  | Display  |
| 3  | Rotary knob: The rotary knob can be turned clockwise or counter-clockwise to highlight the desired item. Press the rotary knob to select the item.   |
| 4  | Main menu  |
| 5  | NIBP measurement start/stop: Press to inflate the cuff and start blood pressure measurement. During the measurement, press the button to stop the measurement.   |
| 6  | Audio alarm pause/OFF: This button can be set up to pause or permanently turn OFF the audio alarm. See <i>Section Audio Alarm Paused</i> , and <i>Section Audio Alarm OFF</i> for details.   |
| 7  | Alarm reset: Press to reset the alarm system.  |
| 8  | AC power indicator: <ul style="list-style-type: none"><li>• ON: when AC power is connected</li><li>• OFF: when AC power is not connected.</li></ul>  |
| 9  | Battery indicator: See <i>Section Battery Power Indicator</i> for details.   |
| 10 | Power-ON indicator: <ul style="list-style-type: none"><li>• ON: the monitor is in working condition.</li><li>• OFF: the monitor is not in working condition.</li></ul>   |
| 11 | ON/OFF power switch: <ul style="list-style-type: none"><li>• Press the button to power ON the monitor.</li><li>• Press and hold the button for three seconds to power OFF the monitor.</li><li>• Unplug the power cord to completely disconnect the AC power supply.</li></ul>                                   |

### 3.1.2 Side View

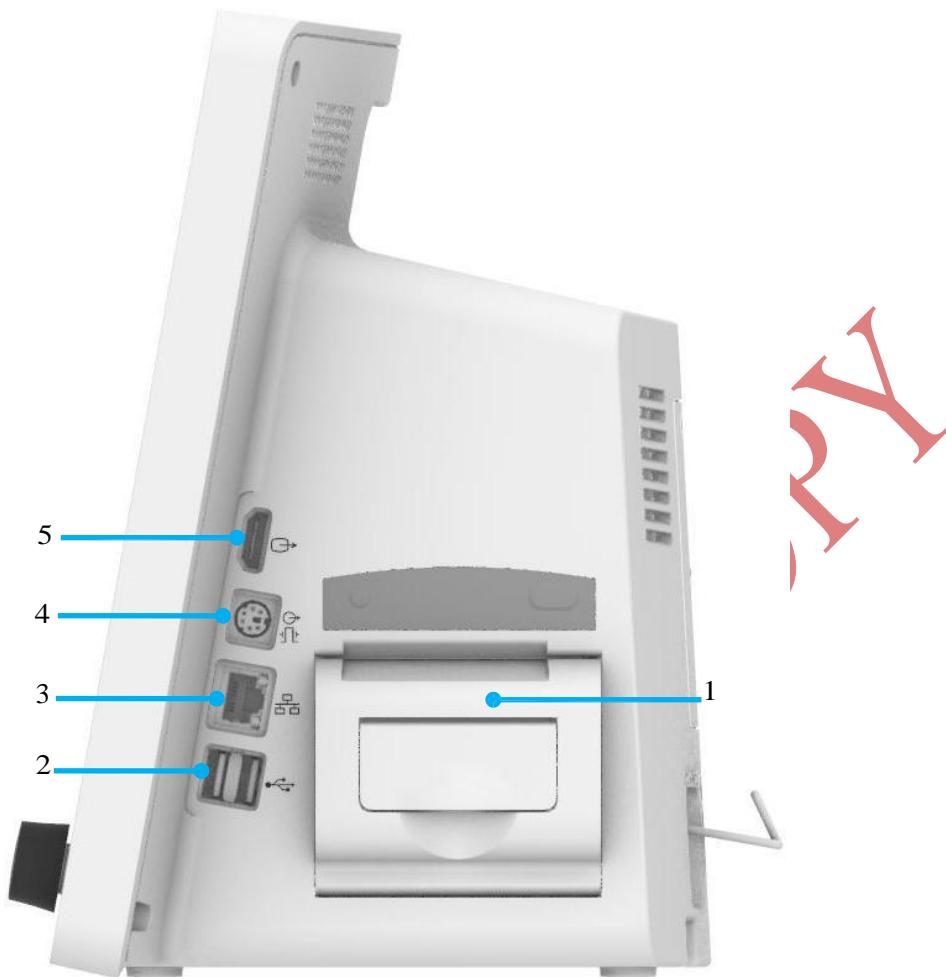
#### 3.1.2.1 Left Side



The parameter configuration of each model is slightly different. Take one as an example:

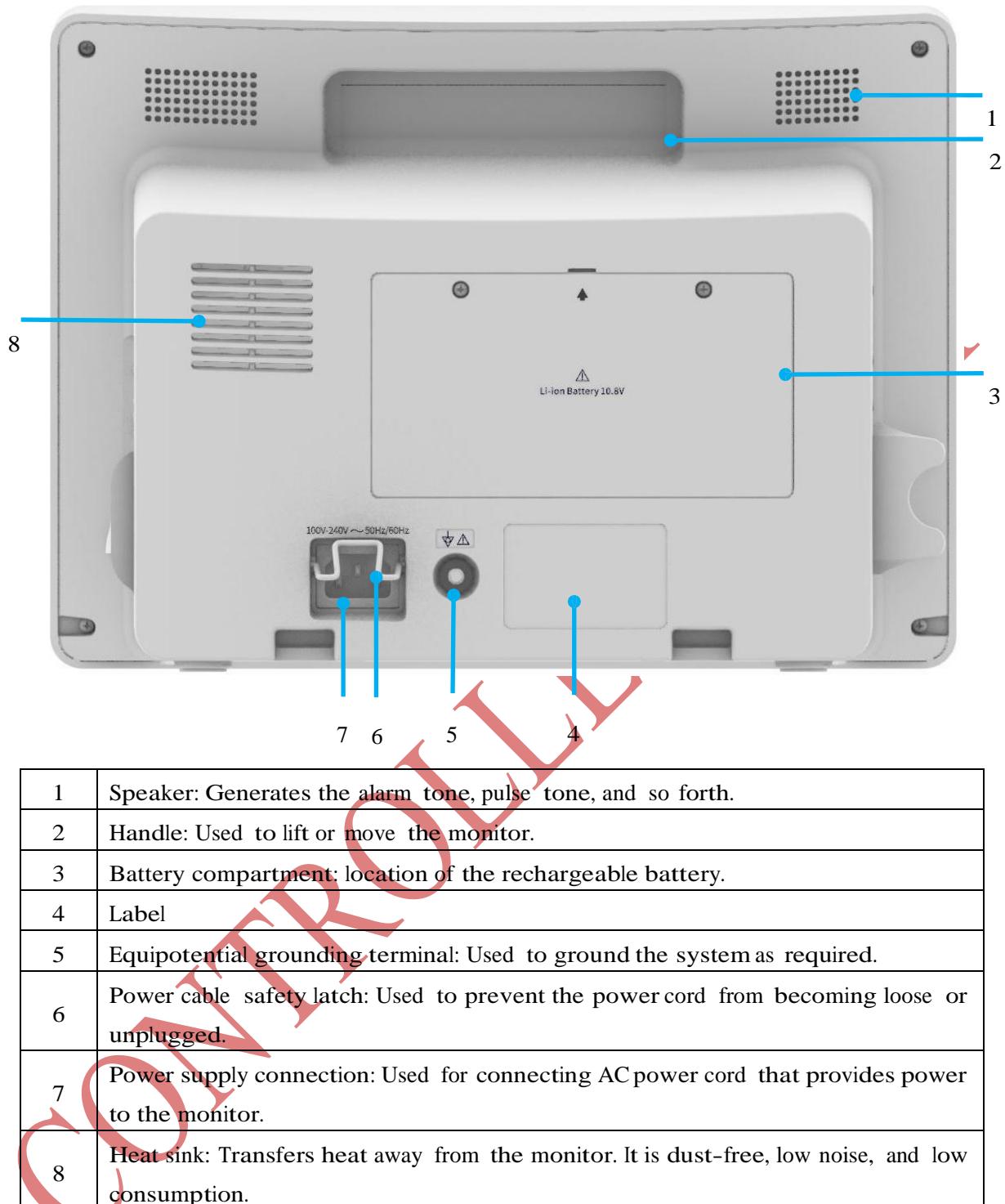
|   |  |
|---|--|
| 1 | TEMP probe port: Allows for the TEMP parameter measurement.                              |
| 2 | ECG cable port: Allows for the ECG parameter measurement.                                |
| 3 | SpO <sub>2</sub> sensor port: Allows for the SpO <sub>2</sub> parameter measurement.     |
| 4 | NIBP cuff port: Allows for the NIBP parameter measurement.                               |
| 5 | CO <sub>2</sub> holder (Optional): Allows for the CO <sub>2</sub> parameter measurement. |
| 6 | C.O. cable port (Optional): Allows for the C.O. parameter measurement.                   |
| 7 | IBP cable port (Optional): Allows for the IBP parameter measurement.                     |

### 3.1.2.2 Right Side



|   |   |
|---|---|
| 1 | Recorder: See <i>Section Recording</i> for details.   |
| 2 | USB ports: Support USB 2.0 output. Allows communication from the monitor to approved USB devices (for example, USB flash drive, barcode scanner, mouse and keyboard).   |
| 3 | Network port: Enables software upgrades and connects the monitor to the central monitoring system (also named as MFM-CMS) via standard network cable, which enables MFM-CMS to achieve bidirectional communication with the monitor.  |
| 4 | Multifunction port is used for the following: <ul style="list-style-type: none"> <li>• Nurse call port: connects the monitor to the hospital nurse call system. Alarm alerts can be communicated through the nurse call system if configured.</li> <li>• Analog output: used to communicate waveform outputs.</li> <li>• Defibrillator synchronization: used to output the defibrillator synchronization signal.</li> </ul> |
| 5 | Video output port: Allows for video output.   |

### 3.1.3 Rear View



**NOTE: In some special cases, if the monitor crashes, a tone sounds to inform the user. The monitor will restart automatically.**

### 3.1.4 Applied parts

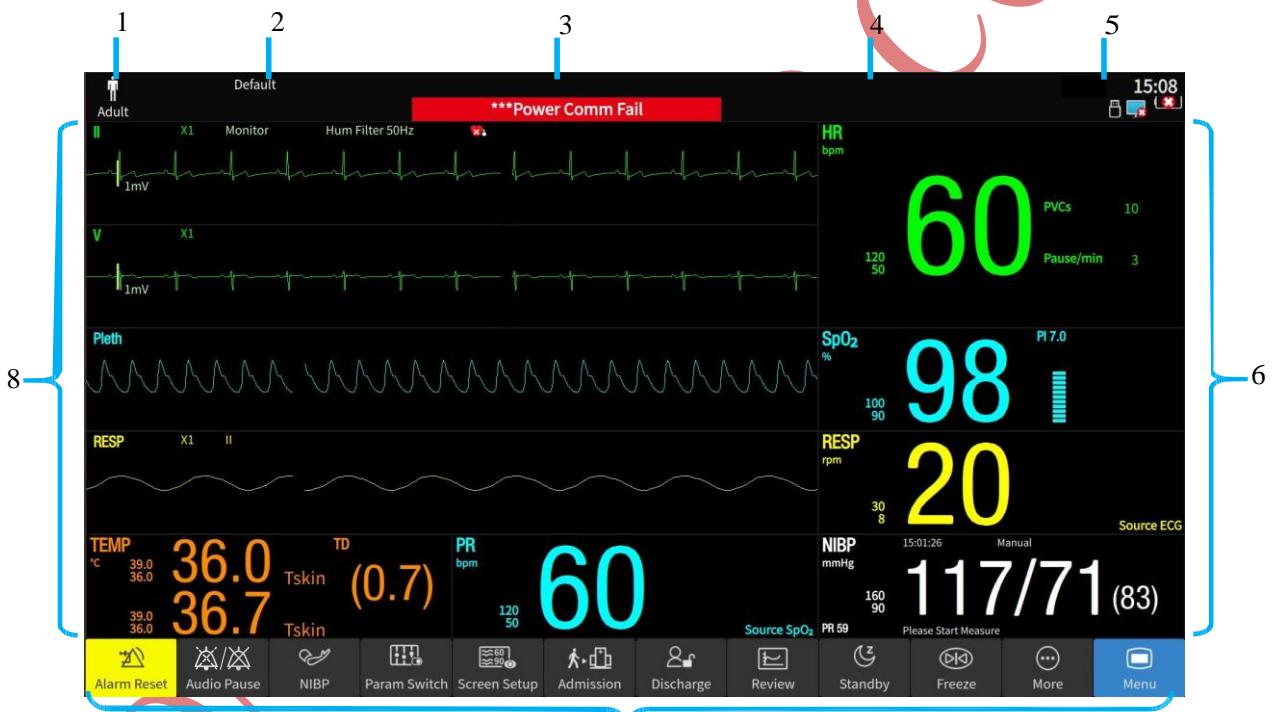
The applied parts of the monitor are:

- ECG cable and electrode
- NIBP cuff
- TEMP probe

- SpO<sub>2</sub> sensor
- IBP transducer  
(Optional)
- C.O. sensor  
(Optional)
- CO<sub>2</sub> sampling  
line(Optional)

### 3.2 Operating and Navigating

Everything needed to operate the monitor is available on the screen. Every element on the screen is interactive. Screen elements include measurement data, waveforms, screen keys, information fields, alarms fields and menus. The configurability of the monitor means the same element can often be accessed in multiple ways. For example, an item can be accessed through its on-screen setup menu, by pressing a hard key, or by touching a shortcut key.



|   |   |
|---|---|
| 1 | Patient information area  |
| 2 | Current profile   |
| 3 | Technical alarm and prompts: <ul style="list-style-type: none"> <li>• Displays prompt information at the top.</li> <li>• Displays technical alarm information at the bottom.</li> <li>• This area can be selected to enter the technical alarm list.</li> </ul> |

|   |   |
|---|---|
| 4 | Physiological alarms: <ul style="list-style-type: none"><li>• Displays high-level physiological alarms at the top.</li><li>• Displays medium-level and low-level physiological alarms at the bottom.</li><li>• This area can be selected to enter the physiological alarm list.</li></ul> |
| 5 | System information: Displays system time, battery status, screen brightness, volume, and so forth. For more information, see On-screen Symbols. This area can be selected to expand the system information area.  |
| 6 | Parameter measurement values: This area can be selected to enter the parameter setup menu.  |
| 7 | Shortcut key area   |
| 8 | Parameter area/waveform area: This area can be selected to enter the parameter setup menu.  |

## On-screen Symbols

| Symbol | Description               | Symbol | Description  |
|--------|---------------------------|--------|--|
|        | Patient type: Adult       |        | Patient type: Pediatric  |
|        | Patient type: Neonate     |        | Battery status - see Section Battery Status on the Main Screen for more symbols for different situations |
|        | Screen brightness         |        | Alarm volume   |
|        | QRS volume                |        | Select to enter the system time setup menu   |
|        | Key volume                |        | Parameter alarm is turned off.   |
|        | High-level alarm          |        | Medium-level alarm   |
|        | Low-level alarm           |        | Wireless network signal strength   |
|        | Alarm reset               |        | USB flash drive is ready   |
|        | Audio alarm paused        |        | USB flash drive is inserted in   |
|        | Audio alarm off           |        | NFC mode   |
|        | MFM-CMS connection status |        | Gateway connection status  |

### 3.2.1 Using Keys

The monitor has four different types of keys. If the key volume is enabled, the monitor gives a normal key tone when the operation is valid.

#### 3.2.1.1 Permanent Keys

A permanent key is a graphical key that remains on the screen providing quick access to functions.



Main menu - enters the main setup menu.



Alarm reset - confirms ongoing alarms and resets the alarm system.



Alarm mute - pauses or permanently turns off the alarm tone.



More - shows more shortcut keys

### 3.2.1.2 Shortcut Keys

A shortcut key is a configurable graphical key located at the bottom of the main screen. It provides quick access to functions. The selection of shortcut keys available on the monitor depends on the monitor configuration and on the options purchased. Select the shortcut keys to be displayed on the main screen through Menu > Screen > Shortcut Keys (password protected). Adjust the shortcut key sequence as needed. See *Section Changing Screen Layout* for details.



Quickly admit a patient



Discharge a patient



Enter the review menu



Parameters setup



Screen setup



Freeze or unfreeze waveforms



Enter the configuration management menu



Enter the standby mode



Enter the score menu  
(not applicable in neonate mode)



Enter alarm setup menu



Start or stop NIBP measurement



Start NIBP STAT measurement



Stop all NIBP measurements



Zero the IBP sensor



Enter the C.O. measurement interface



Start or stop real-time recording



Enter the night mode



Enter the intubation mode



Enter 24h ECG  
Summary menu



Enter 24h NIBP  
Summary interface



Enter the privacy mode

### 3.2.1.3 Hardkeys

A hardkey is a physical key on the monitor, such as the ON/OFF power button.

### 3.2.1.4 Pop-up Keys

Pop-up keys are task-related graphical keys that appear automatically on the screen when required. For example, the Confirm pop-up key appears only when a change needs to be confirmed.

## 3.2.2 Using the Touch Screen

### 3.2.2.1 Gesture Control

Touch or swipe the touch screen:

- Touch the screen to select the options in a menu or from the list.
- Touch parameter or waveform area to enter the setup menu.
- Swipe the menu or list up and down to show more options.
- Swipe the screen left or right to change the screen layout.

### 3.2.3 Using the On-Screen Keyboard

The on-screen keyboard allows the user to enter information. The keyboard only appears when the user needs to add text or values. To operate the keyboard:

1. Enter the necessary information.
2. Select to delete a single character or select to clear the entire entry.
3. Select to access uppercase letters.
4. Select OK to confirm the entry and exit the on-screen keyboard.

## 3.3 Operating Mode

### 3.3.1 Demo Mode

#### WARNING

Demo Mode is for demonstration purposes only. Demo mode should not be used during patient monitoring. In Demo Mode, all stored trend information is deleted from the monitor memory

**WARNING**

NOTE: The default initial password of Demo Mode is demo3045. Selecting Modify Demo Password can be used to change the password. Authorized representative can be contacted to reset the password if needed.

- To change from operating mode to Demo Mode: select Menu > System > Demo > Demo Mode and enter the required password.  
After entering Demo Mode, the monitor will perform the following:
  - Stores demonstration data and clears previously stored data from memory.
  - Simulates all real-time data and historical data rather than display actual patient data.
- To exit Demo Mode: select Menu > System > Demo > Exit Demo Mode or restart the monitor.

### 3.3.2 Standby Mode

Standby mode is used when a patient must temporarily leave the monitor. In standby mode:

- The monitor stops monitoring patients and stores previously monitored data.
- The monitor will not respond to alarms and prompts.

To enter standby mode, choose either of the following:

- Select the shortcut key  on the main screen. The monitor will ask the user to confirm the operation. If Confirm is selected, the monitor enters standby mode.
- From the Discharge dialog, select Standby after Discharge.

To exit standby mode, touch anywhere on the screen and choose either of the following from the displayed message:

- Select Current Patient to exit standby mode and resume monitoring the current patient.
- Select New Patient to exit standby mode and admit a new patient.

### 3.3.3 Night Mode

**PRECAUTION**

The following settings should be verified after entering Night Mode: screen brightness, alarm volume, QRS volume, and key volume. Be aware of the potential risk if the setting value is low.

NOTE: The following occurs in Night Mode

- Key volume, QRS volume, pitch tone, and NIBP end tone are muted.
- Alarm volume and screen brightness are set to minimum.

- Key volume, QRS volume, pitch tone, alarm volume, screen brightness, and NIBP end tone settings are unavailable.

To switch to Night Mode, select either of the following:



- Select the Night Mode key on the main screen.
- Select Menu > Screen > Night Mode Setup > Night Mode.

When entering the night mode, the alarm light is on by default and can be turned off by the user as needed. To change the setting of the alarm light in night mode, follow these steps:

1. Select Menu > System > User Maintain and enter the password.
2. Select Alarm Setup and set Night Mode Alarm Light Setup to ON.
3. Select Menu > Screen > Night Mode Setup, turn off the Alarm Light. To exit Night



Mode, select the shortcut key or Quit Night Mode.

### 3.3.4 NFC Mode

NOTE: The abbreviation “NFC” is not related to near field communication.

NFC mode is designed to constantly observe the HR physiological alarm. In NFC mode, the HR physiological alarm cannot be deactivated. To configure NFC mode, select Menu > System > User Maintain > Alarm Setup and choose NFC Mode which can be set to ON or OFF. NFC mode is OFF by default.

In NFC mode:

- The HR physiological alarms are always ON and cannot be set to OFF.
- The audio alarm cannot be set to OFF permanently.
- The audio alarm OFF status will end and the monitor will change to normal alarm response status. Pause Time will automatically switch to 120 s, which can be set to 60 s, 120 s, or 180 s manually.
- The audio alarm paused status is not affected by entering NFC mode.
- The **NFC** symbol is displayed in the HR parameter area.

After exiting NFC mode:

- The HR physiological alarms are still ON and can be set to OFF.
- Pause Time setting is unchanged and can be set to Permanent.
- The **NFC** symbol is no longer displayed.

### 3.3.5 Privacy Mode

The privacy mode is a special clinical monitoring mode. In the privacy mode, the monitor does not display patient information and monitoring data. This provides controlled access to patient data and ensures confidentiality.

Only if the monitor is connected and admitted by MFM-CMS, the privacy mode can be activated. Press the shortcut key  or select Menu > Screen > Display Setup > Privacy Mode, the monitor enters into privacy mode after confirmation.

In privacy mode:

- The screen displays message: Privacy mode and View the monitoring information on the server.
- Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS. The patient data is only visible at the MFM-CMS.
- No visual alarm indications and alarm sounds are issued.

The monitor exits privacy mode under any of the conditions:

- Touching anywhere on the screen or pressing any hardkeys.
- Battery Low alarm or Data Disconnected alarm occurs.
- The monitor is disconnected with MFM-CMS.
- Using the barcode scanner.

## 3.4 Changing Monitor Settings

### 3.4.1 Adjusting Screen Brightness

NOTE: If the monitor is battery powered, it is recommended to adjust the screen brightness to a lower level to optimize battery usage.

To change the screen brightness:

1. Click the system information area and adjust .
2. Or select Menu > Screen > Display Setup and set the screen Brightness.

### 3.4.2 Changing Date and Time

#### PRECAUTION

Change to date and time will affect the storage of trend data and may result in a loss of data.

To change the date and time, see *Section Setting Date and Time*.

## 3.5 Adjusting Volume

### 3.5.1 Adjusting Key Volume

The key volume is audible when any field is selected on the monitor. To adjust the key volume:

1. Select  in the system information area.

2. Select the appropriate setting for the key volume. The volume ranges from 0 to 10. If it is set to 0, the key volume will be OFF.

### 3.5.2 Adjusting Alarm Volume

To change the alarm volume:



1. Select in the system information area or select Menu > Alarm > Alarm Setup > Alarm Volume.
2. Select the appropriate setting for the alarm volume. The volume ranges from 1 to 10.

### 3.5.3 Adjusting QRS Volume

NOTE:

1. Changing the QRS volume in the system information area also changes the QRS volume in the ECG Setup and PR Setup menus.
2. If the QRS volume is set to 0, the volume will be OFF.
3. The QRS frequency has positive correlation with the measurement value.

QRS volume is from HR or PR depending on the setting of the QRS tone source. To change the QRS volume:



1. Select in the system information area or select QRS Volume in ECG Setup or PR setup menu.
2. Select the appropriate setting for the QRS volume. The volume ranges from 0 to 10.

## 3.6 Setting Language

To change the language:

1. Select Menu > System > User Maintain > Other Setups.
2. Select Language and choose the desired language from the list. The setting will take effect immediately.

## 3.7 Setting Keyboard Language

NOTE: The keyboard language will restore to the default language when the system language changes. The default keyboard language varies in different system languages.

The monitor is equipped with both Chinese and English keyboards. To change the keyboard language:

1. Select Menu > System > User Maintain > Other Setups > Keyboard Language.
2. Select the desired language from the list.

## 3.8 Setting Parameter Unit

To select the parameter unit:

1. Select Menu > System > User Maintain > Unit Settings.
2. Select the unit for each parameter.

NOTE: The unit % for CO<sub>2</sub> gases indicates vol%.

### 3.9 Using the Barcode Scanner

The monitor supports both a linear (1D) barcode scanner and two-dimensional (2D) barcode scanner (Honeywell Xenon 1900, Zebra Symbol DS2208/DS2278).

Set up the barcode scanner according to the scanner user manual prior to first use.

- Program the scanner for USB HID barcode scanner.
- For the Honeywell Xenon 1900 barcode scanner, scan the barcode before connecting the scanner to the monitor.



- Program a carriage return.
  1. Connect the barcode scanner to a monitor USB port.
  2. When the scanner is connected for the first time, the monitor will ask if the new USB device is a scanner. Choose Scanner to add the barcode scanner to the scanner management list and enter the required password to enable the barcode scanning.
  3. Select Menu > System > User Maintain and enter the required password to define the barcode in Scanner > Barcode Setup. Set patient the start and end codes according to the hospital data format. Set the male and female codes to distinguish the patient gender before using the scanner.
  4. See *Section Barcode Admit* for admitting patients by barcode scanner.

In addition, check relevant scanner information or delete specific barcode scanner in

Scanner > Scanner Management.

### 3.10 Checking Your Monitor Version

To check the monitor software version, select Menu > System > About.

### 3.11 Checking Software License

The software license is required to run specific functions in the monitor. To check the software license, select Menu > System > License.

## Chapter 4 Networked Monitoring

NOTE: Some network-based functions may be limited for monitors on a wireless network compared to those on a wired network.

The monitor can connect to both the hospital wired and wireless network. When the monitor is networked, a network symbol is displayed on the screen.

### 4.1 Cybersecurity Measures

#### 4.1.1 Personal Information Safety

##### **PRECAUTION**

- 1 Monitor access and operation is restricted to authorized personnel only. Only staff with a specific role should be assigned the right to use the monitor.
- 2 All device components containing personal information (other than removable media) should be physically secured (for example, components should not be removable without tools).
- 3 After patient discharge, patient data should be archived according to the hospital protocol (when applicable) before it is deleted from the monitor memory.
- 4 The monitor should only be connected to devices authorized or approved by the manufacturer. Only use the monitor as originally specified by the manufacturer. This includes, but is not limited to, approved software, software configuration, and security configuration.
- 5 All passwords must be protected to prevent unauthorized changes. Only the manufacturer's service personnel is allowed to modify the Factory Maintain settings.
- 6 All USB flash drives should be checked for viruses prior to use.
- 7 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It is recommended to use Windows Defender firewall or a firewall that can defend against DoS and DDoS attacks and allow for updates.
- 8 DoS and DDoS protection of the router or switch must be turned on for defending against attacks.
- 9 Before sending the monitor back to the manufacturer, all patient data must be removed from the monitor before being returned.
- 10 To protect the patient's personal health information including data displayed and stored in the monitor, unauthorized personnel must not have access to the monitor.
- 11 The encryption function should be turned ON (it is set to ON by default) to avoid malicious tampering and theft of data transmitted over the network. With the encryption function ON, the monitor authenticates the accessed devices and encrypts the transmitted data.

NOTE: Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data.

Protecting personal health information is a major component of security strategy. To protect the personal information and provide proper monitor performance, precautions must be taken in accordance with local laws and regulations and the institution's policies.

Health care organizations or medical institutions should take steps to protect systems from internal and external threats. A plan to protect patient safety and personal health information includes physical restrictions to limit access by unauthorized personnel, operational and administrative safeguards, and technical safety practices to limit external system access.

The following should be considered when building the networking environment:

- If a wireless router is used, the wireless router MAC address filtering function must be ON and the monitor MAC address added to the rule list. The wireless router only allows devices in the rule list to access the wireless network.
- If building a VLAN, assign the LAN ports where the approved switch port, monitor, and external system are joined to the same VLAN and isolate it from other VLANs.

#### 4.1.2 Network Security

For more security operations, select **Menu > System > User Maintain** and enter the user maintenance password. Then select **Network Setup > Network Security**. From the network security menu:

- Set Firewall to ON to protect against network attacks.
- Click Firewall Rules to check rule details.
- Enable the Packets Limit Switch and set Packets Limit value for traffic monitoring. If the monitor is under DoS attack and the data-traffic-per-minute exceeds the preset threshold, the monitor will trigger the “Network Traffic Abnormality” alarm. At the same time the network will disconnect for five minutes. After five minutes, the network will reconnect and the alarm will no longer be displayed.

For Certificate Management, see Section Managing Certificates for further information.

#### 4.1.3 Login Management

NOTE:

- 1 When accessing the monitor for the first time, follow the prompts to set the User Maintain password.

- 2 The monitor will display “More than 5 consecutive password errors” if any password is entered incorrectly five times or more in a row.
1. Select Menu > System > User Maintain and enter the user maintenance password.
  2. Select Login Management.

From the login management menu:

- Set Auto Login to ON or OFF. When it is set to ON (default), the main menu can be accessed directly. When set to OFF, a password is required for identity authentication.
- Select User Login Timeout to set the login timeout period. The screen will lock if the login information isn't entered in the specified period. The password can be re-entered after the timeout period. If the password is forgotten, reset the user maintenance password by entering the factory maintenance password. When set to never (default), there is no need to re-enter the password after the successful login.
- Select Modify User Password. Follow the prompts to change the user password. Change the password periodically. A combination of words and numbers is recommended. If Old Password is forgotten, contact a service personnel for help.

## 4.2 Configuring the Network

The monitor can be connected to the central monitoring system through wired LAN or wireless LAN.

### 4.2.1 Selecting a Network Type

To select a network type, follow these steps:

1. Select Menu > **System** > **User Maintain**, and enter the password.
2. Select **Network Setup** > **Connections** and set **Connection Type** to **Wired** or **WLAN**.

### 4.2.2 Setting the Wired Network

To set the wired network, follow these steps:

1. Select Menu > System > User Maintain, and enter the password.
2. Select Network Setup > Connections and set Connection Type to Wired.
3. Select Config and set Mode to Manual or Auto.
  - Auto: the monitor automatically gets the IP address.

- Manual: Local IP address, Subnet Mask and Gateway need to be manually entered.
4. Set the DNS address if needed.

### 4.2.3 Setting the Wireless Network

#### WARNING

- 1 Before connecting the monitor to the patient, the Connection Type (wired or WLAN) should be selected. The Connection Type cannot be changed during monitoring as the data may not be transmitted to the central monitoring system.
- 2 If Wi-Fi is unavailable, restart the WLAN to restore Wi-Fi function for patient safety.
- 3 If enterprise encryption uses an inappropriate self-signed certificate, there is a risk of information leakage! Do not connect the monitor to untrusted hotspots!

#### NOTE:

- 1 Physical obstacles such as walls may interfere with data transmission or even cause data loss.
- 2 When signal intensity is level 2 or less, the signal may be unstable and the quality of the signal transmission may be degraded.
- 3 When the monitor is connected to MFM-CMS via the wireless network, the router should be secured using a high complexity, non-dictionary password.
- 4 Network disconnection does not have an impact on local monitoring functions.

A Wi-Fi module is an option that can be included with the monitor. To set up the wireless network:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > Connections** and set **Connection Type** to **WLAN**.
3. Select **WLAN** and set **Frequency Band** to **2.4GHz, 5GHz** or **Auto**. Restart the monitor and the available networks will be listed in WLAN window. The wireless network can be selected from the WLAN window or entered manually.

To select a network from the list:

- a. Choose a network from the window to check the network encryption information. A prompt will request the network password if needed.
- b. Enter the password and select **Connect**.

To enter a network manually:

- a. Select **Other** and enter the information as needed.
- b. Select **Connect**.

- c. For WPA2-PSK, enter the network name and password.
- d. For WPA2-EAP, enter the network name, EAP method (TLS/TTLS/PEAP), inner authentication (EAP-MSCHAPV2/any/MSCHAPV2), domain, username, and password as required. When the EAP method is set to TLS, import the certificate according to *Section Managing Certificates* and select the corresponding certificate from the Certificate List.

#### 4. Select **Config** to set **Mode**, **Local IP address**, **Subnet Mask** and **Gateway**.

When the monitor is successfully connected to the selected network, the Wi-Fi icon  will be displayed in the system information area and the Wi-Fi currently in use will be displayed at the top of the WLAN window.

Wi-Fi signal strength symbols:

|   |                                |
|---|--------------------------------|
|    | Wi-Fi signal strength: Level 4 |
|    | Wi-Fi signal strength: Level 3 |
|   | Wi-Fi signal strength: Level 2 |
|  | Wi-Fi signal strength: Level 1 |

Select  to review the previously connected network. After selecting a network, select **Delete** or **Join**.

If the encryption information of the currently connected network is modified, the network will automatically disconnect and attempt to reconnect. Select  first to ignore this network and connect manually. If the encryption information or SSID is modified for an unconnected network, disconnect from the currently connected network and select  to choose the updated network.

Select **Disconnection Statistics** to view network disconnection details. Select **Export** to export the statistics data to the specified USB drive.

In the **Wi-Fi Maintain** menu, enable the **Background Scan Switch** and select **Background Scan Channel** to search for a stronger Wi-Fi signal in the specified channels. Roaming threshold and lag can also be viewed.

Network symbols:

| Symbol  | Description                        |
|---|------------------------------------|
|  | View previously connected network  |
|  | Refresh network list               |
|  | The network is password protected. |

### 4.3 Managing Certificates

The monitor provides built-in certificate authority (CA) certificates and supports importing a new CA and certificate.

#### 4.3.1 Importing Certificates

The monitor supports the import of the monitor certificate and CA from the USB flash drive.

To prepare the directory:

1. Create a “cert” folder in the root directory of the USB flash drive.
2. Place the certificates to be imported into the directory.

To prepare the security settings:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > Network Security**.

Before importing the certificate, the CA that assigned the certificate first must be imported to make the monitor trust this CA. When importing the certificate, the CA which assigned this certificate must be selected because the monitor can confirm the imported certificate is a valid one.

To import the CA:

1. Select **CA Certificate** to show the CA list of the monitor.
2. Select the specific certificate to show the details.
3. Select **Import Certificate > CA** to import the desired CA to the monitor.

#### 4.3.2 Certificate Management

**NOTE: The monitor supports CA and certificates with .cer, .crt, .pem, and .key suffixes.**

To view a certificate's details:

1. Select **Certificate Management** and a list of monitor certificates is displayed.
2. Select the specific certificate to show the details.

To import a certificate:

1. Select **Import Certificate** to access the certificate management menu.
2. Select the USB flash drive where the certificate is located.
  - **CA:** Select the CA which assigned this certificate.
  - **Certificate:** Select the certificate from the USB flash drive.
3. Select the Private Key and input the password as required.

4. Select **Import Certificate** button to import the certificate to the monitor. To select a certificate:

1. Select **Select Certificate** to choose the certificate currently used by the monitor.
2. Restart the monitor to retain the settings change.

## 4.4 Bed View

The **Bed View** window allows users to view the following:

- The alarm status and alarm information of up to eight beds on the same network.
- The real-time parameter values and waveforms from the main bed.

**NOTE:**

- 1 **The IP addresses of the monitors configured with bed view function should share the same network segment. The IP addresses of the monitors on the same LAN should be unique from each other; Bed view function is not available when an IP address conflict exists.**
- 2 **To ensure optimal functioning of the Bed View, an adequate stable network connection is required.**
- 3 **The bed view results are for reference only. Clinical decisions should only be made based on information from the local bedside device.**
- 4 **You can also view this monitor from other remote devices. This monitor can be viewed by at most eight remote devices at the same time, in which one remote device can watch this monitor's waveforms.**

### 4.4.1 Configuring Bed View

The monitor supports to observe alarm conditions and view real time physiological data from patients on other networked monitoring devices. To configure the bed view function:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > Bed View Setup**. Bed View Setup menu options:
  - Enable **Remotely View Other Monitors**: allow to view the realtime screen of one remote monitor (the main bed) on your monitor. Restart your monitor to make the settings effective.
  - Enable **Remotely Viewed by Other Monitors**: allow your monitor to be viewed by other remote devices.
  - Enable/disable **Encryption Switch**.

- Enable **Patient Information before Connection**: display the patient information in the device management list on the remote monitors when your monitor is not yet connected.
- Enable **Distributed Alarm for Bed View**: display the alarms from the remotely viewed monitors in the alarm area of the main screen after exiting the Bed View window.
- **Parameter Selection**: Choose parameters to be displayed in the Bed View window from the pop up.

#### 4.4.2 Accessing the Bed View Window

Before accessing the **Bed View** window, make sure the bed view function is configured on the monitor. See *Section Configuring Bed View* for details. To access the Bed View window, select **Menu > Screen > Screen Setup** and choose **Bed View**.

The background color indicates the alarm status of the corresponding bed:

| Background Color | Description  |
|------------------|--|
| No color         | The device is normally connected and no alarm is occurring to the bed.   |
| Grey             | The device is disconnected.  |
| Red              | The high-level alarm occurs to the bed and currently is the highest alarm level on the bed.                                    |
| Yellow           | The medium-level alarm or low-level physiological alarm occurs to the bed and currently is the highest alarm level on the bed. |
| Blue             | The low-level technical alarm occurs to the bed and currently is the highest alarm level on the bed.                           |

If configured, after exiting the Bed View window, the monitor cyclically displays the highest priority alarm for each bed in the alarm area of the main screen.

#### 4.4.3 Adding a Bed

Add the desired remote devices, and then the alarms from these devices can be displayed on the monitor.

To add a remote device:

1. Select **Patient List > Manage Devices** and select the desired devices from the list. A maximum of eight beds can be selected. Click **Confirm**. The added bed is indicated by a check mark (✓) at the left of the bed list. The monitor use the following symbols to indicate the device connection status:



Connection success.



Connection failed.



IP address conflict.



Device offline.

2. Select **Patient List** and then select a patient for each bed from the patient list. The selected beds will appear in the **Bed View** window.

#### 4.4.4 Removing a Bed

To remove a remote device, select a bed from Patient List and then select Clear Bed, or select Clear All.

#### 4.4.5 Displaying the Main Bed

Directly click on the bed of the Bed View window or select Patient List > Enter Bed to view the real-time parameters, waveforms and alarms of the main bed, and monitor the alarm of other beds.

#### 4.4.6 Alarm Audio Pause for Remote Devices

To pause the audio alarm of the remote device, select , enable Audio Pause and then set Pause Time.

#### 4.4.7 Resetting Alarms for Remote Devices

To reset the alarms of the remote device, select , select Alarm Reset.

### 4.5 Connecting the Monitor to Central Monitoring System

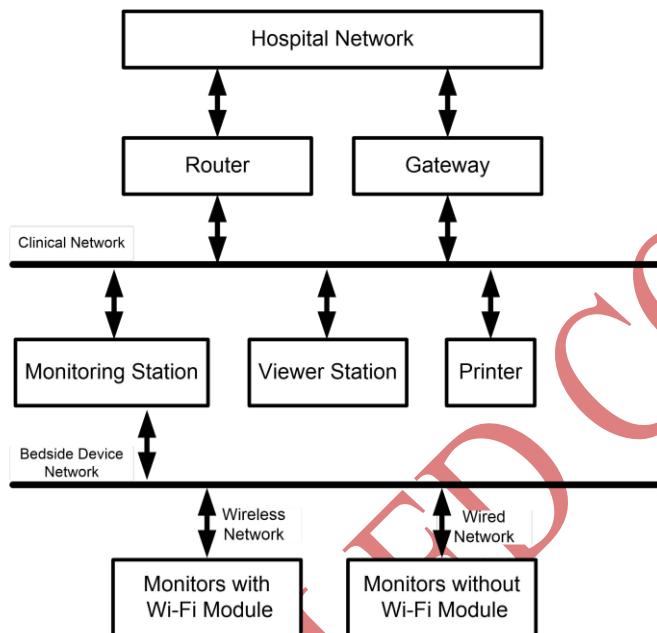
#### NOTE:

- 1 Due to network transmission delay, data viewed at the MFM-CMS has a delay of up to 10 seconds when compared with data generated at the corresponding monitor. To avoid potential patient injury, do not rely on MFM-CMS when it comes to time-critical observations.
- 2 Due to electrosurgical unit (ESU) interference, while using the monitor in an operating room environment, the monitor should be connected via a wired connection instead of wireless networking.
- 3 When connecting the monitor to the central monitoring system, it is recommended to isolate the network from the hospital Intranet system using VLAN for network security purposes. Only trusted devices are allowed to join the VLAN network.

When the monitor is connected to the central monitoring system:

- Patient information, real-time monitoring or measurement data is sent from the monitor to the central monitoring system.
- Real-time monitoring information is displayed on both the monitor and the central monitoring system, and the central monitoring system can perform some bilateral control.

The central monitoring system network is as shown below.



For more information about the central monitoring system communication, see *MFM-CMS Central Monitoring System (I) User Manual*.

#### 4.5.1 Setting the Server

To set the server information:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > Connections**.
3. Enable **Server Connection** to ON. When it is set to OFF, the monitor disconnects from the server.
4. Enable **Server Encryption** to ON to encrypt the data.
5. Select **Server Address** to enter the server IP address or domain.
6. Select **Server Port** to enter the server port.
7. Select **Server Name** to enter the server name (Server Name is the CN field of the server certificate).
8. Enable **Remote Control Switch** to allow the remote control from the central monitoring system.

9. Select **Certificate** to choose the certificate currently used by the monitor. The setting in **Network Security > Certificate Management > Select Certificate** also changes accordingly.

## 4.6 Connecting the EMR System

The monitor supports HL7 protocol to upload data to the EMR system. To connect the EMR System:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > HL7**

Setup. HL7 Setup menu options:

- Set **Transfer Switch** to ON.
- Set **Connection Type** to **TCP Client**.
- Set **Encryption Switch** to ON or OFF. When it is set to ON, the CA of the server must be imported. See [SectionImportingCertificates](#)for details.
- Set **Send Alarms** to ON or OFF. When it is set to ON, **HL7 Periodic Alarm** should be configured.
- Set **Parameter Period**.
- Select Server Address to set the IP address or domain for the server receiving the data.
- Set the server **Port**.

For more information about HL7 communication, see *HL7 Communication Protocol Specifications*.

## 4.7 Connecting the Monitor to Gateway

The monitor can be connected to the Gateway, which provides clinicians with the capability of viewing and collecting patient data remotely and the data exchange of selected clinical and administrative information between the manufacturer's network and the hospital network.

To configure the Gateway information:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > Gateway**

Setup. Gateway Setup menu options:

- Enable **Gateway Transfer Switch** to ON. When it is set to ON, the monitor can transmit the parameter data to the Gateway.
- Enable **Gateway Encryption Switch** to ON to encrypt the data.

- Select **Gateway IP** to input the IP address or domain of the Gateway. Make sure the monitor share the same server IP with the computer in which the Gateway is installed.
- Select **Gateway Port** to input the port of the Gateway.
- Select **Gateway Target Name** to input the name of the Gateway.
- Select **Certificate** to choose the certificate currently used by the monitor. The setting in **Network Security > Certificate Management > Select Certificate** also changes accordingly.

For more information about Gateway communication, see *Gateway User Manual*.

## 4.8 Using ADT Query

The monitor can obtain patient information from the hospital ADT server through the ADT gateway. To configure the ADT function:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Network Setup > ADT Setup**. ADT Setup menu options:
  - Enable **ADT Query Switch**. When it is set to ON, the monitor can load patient information from the ADT server.
  - Enable **ADT Encryption Switch** to ON.
  - Set **ADT Network Protocol**.
  - Select **ADT Server IP** to enter IP address or domain of ADT Gateway.
  - Select **ADT Server Port** to enter the ADT gateway port.
  - Enter **ADT Server Name** and Authentication Type.

# Chapter 5 Alarms

## **WARNING**

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, for example, an intensive care unit or cardiac operating room.

NOTE:

1. The delay time from onset of ALARM CONDITION to the point where representation of ALARM CONDITION leaves the SIGNAL OUTPUT PART is less than 1 second.
2. The sum of the mean alarm condition delay plus the mean alarm signal generation delay is less than 10 s.

## 5.1 Alarm Category

The monitor provides physiological alarms, technical alarms, and prompts.

### 5.1.1 Physiological Alarms

If one or more physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. See *Section Physiological Alarm Information* for details.

### 5.1.2 Technical Alarms

If one or more technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms cannot be disabled. See *Section Technical Alarm Information* for details.

### 5.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. See *Section Prompts* for details.

## 5.2 Alarm Setup

### 5.2.1 Selecting Alarm Tone Type

To set the alarm tone type:

1. Select **Menu > System > User Maintain** and enter the password.

2. Select **Alarm Setup**, and set **Alarm Tone to Standard**. (Standard alarm sound according to IEC 60601-1-8.)

### 5.3 Alarm Levels

#### WARNING

- 1 The audible alarm system should not be relied on exclusively during patient monitoring. The patient may be harmed if the alarm volume is too low or OFF. The most reliable method of patient monitoring combines close personal monitoring with correct operation of the monitoring equipment.
- 2 The audio alarm must be loud enough to be heard over any background noise

In terms of severity, the device's alarm levels can be separated into three categories: high-level alarms, medium-level alarms, and low-level alarms.

- High-level alarms

A high-level alarm urgently warns the operator of a high priority alarm condition requiring immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury to the patient.

- Medium-level alarms

A medium-level alarm warns the operator of a medium priority alarm condition requiring prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury to the patient.

- Low-level alarms

A low-level alarm reminds the operator of a low priority alarm condition requiring response. The response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury to the patient.

See table below for high-, medium-, and low-level alarm system characteristics.

#### Alarm level indications

| Alarm level | Prompt   |
|-------------|--|
| High        | The tone sounds like “DO-DO-DO-----DO-DO, DO-DO-DO-----DO-DO”, which is triggered once every 6 seconds. The alarm indicator flashes RED, with a frequency of 1.4 Hz to 2.8 Hz. The alarm message flashes with a RED background and *** is displayed in the alarm area. |
| Medium      | The tone sounds like “DO-DO-DO” which is triggered once every 25 seconds. The alarm indicator flashes YELLOW, with a frequency of 0.4 Hz to 0.8 Hz. The alarm message flashes with a YELLOW background and ** is displayed in the alarm area.                          |

| Alarm level | Prompt  |
|-------------|---|
| Low         | The tone sounds like “DO-” which is triggered once every 30 seconds. The alarm indicator is constantly CYAN. The physiological alarm message flashes with a YELLOW background. The technical alarm message flashes with a BLUE background and * is displayed in the alarm area. |

The sound pressure range for standard audible alarm signals is from 45 dB to 85 dB at one meter.

The parameter area has two flash methods to prompt alarms: background flash and text flash. Either method can be selected from **Menu > Alarm > Alarm Setup > Visual Effect:**

- **Text Flash:** text flashes with frequency of 1 Hz.
- **Background Flash:** background flashes with frequency of 1 Hz. When the alarm is reset, the background stops flashing.

### 5.3.1 Changing Technical Alarm Priority Settings

To set the priority of the SpO<sub>2</sub> Sensor Off and SpO<sub>2</sub> No Sensor alarms:

- 1 Select **Menu > System > User Maintain** and enter the password.
- 2 Select **Parameter Maintain > SpO<sub>2</sub> > SpO<sub>2</sub> Sensor Off Alarm Level** or **SpO<sub>2</sub> No Sensor Alarm Level**.

## 5.4 Controlling Alarm

### 5.4.1 Setting Parameter Alarm

#### WARNING

- 1 When the parameter alarm is set to OFF, the monitor does not give an alarm prompt even if an alarm occurs. To avoid endangering the patient's life, this function must be used carefully.
- 2 Setting alarm limits to extreme values may cause the alarm system to become ineffective.
- 3 Prior to monitoring, verify that the alarm limit settings are appropriate for the patient being monitored. Always make sure that necessary alarm limits are active and set according to the patient's clinical condition.
- 4 When monitoring patients that are not continuously attended by a clinical operator, set alarm limits according to the patient's clinical **condition**.

Parameter alarm settings including alarm switch, alarm record, alarm level, and alarm limit are available on the respective alarm setup menu for each parameter. To access

parameter alarm settings menu, use the shortcut key  or select **Menu > Alarm > Alarm Limit**. This menu can also be accessed through via the respective parameter setup menu.

Alarms can only be switched ON or OFF when Alarm Switch Setup is set to ON. To enable:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Alarm Setup**.
3. Set **Alarm Switch Setup to Enable**.

When the parameter alarm switch is OFF, the parameter alarm OFF icon  will be displayed in the corresponding parameter area.

#### 5.4.2 Audio Alarm Paused

**NOTE: If a new alarm occurs while the audio alarm is paused, the new alarm will not sound.**

To temporarily pause the audio alarm, press the hardkey  on the front panel or press the shortcut key  on the screen.

The alarm pause time can be set as desired. The default alarm pause time is 120 s. To set the alarm pause time:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Alarm Setup**.
3. Set **Pause Time to 60 s, 120 s, or 180 s**.

When alarms are paused,

- The audio alarm is OFF and the alarm sound is not issued.
- The visual alarm indications are still displayed.
- The monitor displays the audio alarm paused icon  in the system information area.
- The monitor displays the remaining pause time in seconds with a RED background.
- The shortcut key  is displayed with a RED background.

When the alarm pause time expires, the audio alarm paused status ends and the alarm sound is reactivated. The alarm paused can also be ended by pressing the hardkey

 on the front panel or pressing the shortcut key  on the screen.

### 5.4.3 Audio Alarm OFF

**NOTE:**

**1 If a new alarm occurs while the audio alarm is OFF, the new alarm will not sound.**

**2 Pressing the hardkey  or shortcut key  again can resume the audio alarm.**

To set the audio alarm to OFF:

1. Select **Menu > System > User Maintain** and enter the password.

2. Select **Alarm Setup**.

3. Set **Pause Time to Permanent**.

4. Press the hardkey  or shortcut key . The monitor will prompt: **please confirm whether to activate audio alarm off function?**

5. Select **Confirm**. The audio alarm is now OFF. Selecting **Cancel** keeps the current alarm status. No alarm change is made.

6. Press the hardkey  or shortcut key  again to set the audio alarm to ON.

When the audio alarm is OFF:

- The audio alarm is turned OFF and the alarm sound is not issued.
- The visual alarm notifications are still displayed.
- The shortcut key  is displayed with a RED background.

**Remind signal:** Audio alarm OFF symbol  is displayed in the system information area and the **Audio Off** has a RED background.

To adjust the alarm **Pause Time**, see *Section Audio Alarm Paused*.

When the audio alarm is turned off, the monitor issues a periodical reminder tone. The reminder tone is disabled by default. To enable the reminder tone, select **Menu > System > User Maintain > input user maintenance password > Alarm Setup** and set **Audio Alarm Off Reminder Interval** to **1 min, 2 min, 3 min, 5 min, or 10 min**.

### 5.4.4 Alarm Reset

**NOTE: If a new alarm occurs after the alarm is reset, the new alarm will sound and the alarm reset icon in the system information area will no longer be displayed.**

To reset the alarm:

Press the hardkey  on the front panel and enter the password or select the shortcut key  on the screen.

Alarm reset can be password protected. To set the authority:

1. Select **Menu > System > User Maintain** and enter the password.
2. Select **Alarm Setup** and set **Alarm Reset Authority** to ON.

3. Press the hardkey  or the shortcut key  and enter the password to activate the function.

When the alarm is reset:

- The alarm reset icon  displays in the system information area.
- An alarm sound is not issued until a new alarm occurs. The ✓ symbol is displayed before the alarm information indicating that the alarm is confirmed.
- All latching alarms are cleared.

#### 5.4.5 Setting Alarm Light Status for Alarm Reset

When the alarm is reset, the alarm light illuminates by default. The light can be set to ON or OFF as needed. To change the alarm light:

1. Select **Menu > System > User Maintain** and enter the password.
2. Set **Alarm Light** to **On When Reset** or **Off When Reset**.
  - **On When Reset**: When the alarm is reset, the audio alarm indications of the current alarms are set to OFF and the alarm light remains flashing.
  - **Off When Reset**: When the alarm is reset, both the audio alarm indications and alarm light are set to OFF.

#### 5.4.6 Setting Auto Alarm Limit

To configure the auto alarm limit setting, select **Menu > System > User Maintain > Alarm Setup** and choose **Auto Alarm Limit** which can be set to ON or OFF. If it is set to ON, when a parameter reaches the trigger condition of auto alarm limit, the monitor will automatically calculate the alarm limit and remind the user. After the user's confirmation, the monitor will update the new alarm limit for this parameter.

### 5.4.7 Setting Combined Alarm

The monitor provides multi-parameter combined alarm function, select **Menu > System > User Maintain > Alarm Setup** to set **Combined Alarm** to ON or OFF. The default setting is OFF. When the PR source is SpO<sub>2</sub>, the function is available. When the combined alarm is set to ON and PR alarm source is Auto, the monitor automatically selects PR or HR with higher signal quality index as the alarm source.

## 5.5 Latching Alarms



NOTE: The permanent key on the screen can be used to confirm the latched alarm.

To configure the alarm latching setting:

1. Select **Menu > System > User Maintain > Alarm Setup**.
2. Select **Alarm Latch** and set to ON or OFF.
  - When set to OFF: the alarm notifications end when the alarm condition ends.
  - When set to ON: the visual and audio alarm notifications are still active after the alarm condition ends while the latched alarm time is displayed. The indication lasts until the alarm is confirmed.

## 5.6 Intubation Mode

Intubation mode is suitable for RESP and CO<sub>2</sub> monitoring. During intubation (for example, during general anesthesia), the monitor can be set to intubation mode to eliminate unnecessary alarms. In intubation mode, RESP/CO<sub>2</sub>-related physiological alarms (including **RESP/CO<sub>2</sub> No Breath Detected**) will be OFF and the RESP/CO<sub>2</sub> setup menu is unavailable.

To enter intubation mode:



1. Select the shortcut key or select **Menu > Alarm > Alarm Setup**.
2. Set **Intubation Mode Period** to **3 min** or **5 min**. The default setting is 3 min.
3. Click **Intubation** to start the intubation mode. During the intubation mode, the monitor will display the intubation mode and the remaining time.

To exit the intubation mode, allow the countdown to expire, select **Exit Intubation**



**Mode**, or select the shortcut key . After exiting intubation mode, the monitor will resume RESP/CO<sub>2</sub>-related physiological alarms.

## 5.7 Testing Alarms

When powered ON, the monitor will prompt a “DO-” tone that means the audio operation is normal. The auditory alarm indicators can also be tested. To confirm the

alarm indicator lights are normal: Confirm the technical alarm indicator illuminates in RED, YELLOW, and CYAN.

To further test the individual measurement alarms, perform the measurement on yourself or use a simulator. If necessary, adjust the alarm limits and confirm normal alarm operations.

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# Chapter 6 Alarm Information

## 6.1 Physiological Alarm Information

### WARNING

The physiological alarms including Asystole, Sustain VT, RESP No Breath Detected, SpO2 No Pulse, SpO2 Desat, and CO2 No Breath Detected cannot be set to OFF. Setting parameter alarms to OFF is password protected. For further information, see *Section Setting Parameter Alarm*.

| Message              | Cause   | Alarm level     |
|----------------------|---|-----------------|
| <b>ECG</b>           |   |                 |
| <b>ECG HR High</b>   | HR value is above the upper alarm limit.  | User-selectable |
| <b>ECG HR Low</b>    | HR value is below the lower alarm limit.  | User-selectable |
| <b>ECG ST-X High</b> | ST value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)          | User-selectable |
| <b>ECG ST-X Low</b>  | ST value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)           | User-selectable |
| <b>ECG QTc High</b>  | QTc value is above the upper alarm limit.   | User-selectable |
| <b>ECG ΔQTc High</b> | ΔQTc value is above the upper alarm limit.  | User-selectable |
| <b>Asystole</b>      | No QRS is detected for 4 consecutive seconds  | High            |
| <b>V-Fib/V-Tach</b>  | 4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR $\geq 100$ bpm. | High            |
| <b>Vent Brady</b>    | 5 consecutive ventricular beats, and ventricular HR $< 20$ bpm.   | High            |
| <b>V-Tach</b>        | 5 consecutive ventricular beats and ventricular HR $\geq 100$ bpm.  | High            |
| <b>Sustain VT</b>    | The duration of ventricular tachycardia rhythm $>$ the threshold value that has been set.                               | High            |
| <b>Extreme Tachy</b> | HR $>$ Extreme Tachycardia threshold value that has been set.   | High            |
| <b>Extreme Brady</b> | HR $<$ Extreme Bradycardia threshold value that has been set.   | High            |
| <b>Couplet</b>       | 2 consecutive PVCs  | User-selectable |
| <b>Run PVCs</b>      | $3 \leq$ the number of consecutive PVCs $< 5$   | User-selectable |

| Message                  | Cause  | Alarm level     |
|--------------------------|--|-----------------|
| <b>PVC Bigeminy</b>      | A dominant rhythm of N, V, N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.  | User-selectable |
| <b>PVC Trigeminy</b>     | A dominant rhythm of N, N, V, N, N, V, N, N, V   | User-selectable |
| <b>R on T</b>            | A type of single PVC under the condition that $HR < 100$ , R-R interval is less than 1/3 the average interval, followed by a compensating pause of $1.25 \times$ the average R-R interval (the next R wave advances onto the previous T wave). | User-selectable |
| <b>PVC</b>               | Single PVC detected in normal heartbeats, and the number of consecutive single PVC $\geq 4$ within 30 s.   | User-selectable |
| <b>Tachy</b>             | Adult: RR interval for 5 consecutive QRS complex $\leq 0.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq 0.375$ s.  | User-selectable |
| <b>Brady</b>             | Adult: RR interval for 5 consecutive QRS complex $\geq 1.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq 1$ s.  | User-selectable |
| <b>Missed Beat</b>       | If $HR < 120$ bpm, no beats are detected for 1.75 times average RR interval; or if $HR \geq 120$ bpm, no beats are detected for one second.  | User-selectable |
| <b>Irr Rhythm</b>        | Consistently irregular heart rhythm  | User-selectable |
| <b>Pacer not Capture</b> | No QRS complex detected in 300ms after a pace pulse.   | User-selectable |
| <b>Pacer not Pacing</b>  | No pace pulse detected in 1.75 times RR interval after a QRS complex.  | User-selectable |
| <b>Vent Rhythm</b>       | 5 consecutive ventricular beats, and $20$ bpm $\leq$ ventricular HR $< 40$ bpm.  | User-selectable |
| <b>Wide QRS Tachy</b>    | Meet tachycardia conditions, and QRS wave width $\geq 160$ ms.   | User-selectable |
| <b>Non-Sustain VT</b>    | $3 \leq$ The number of consecutive ventricular beats $< 5$ , and ventricular HR $\geq 100$ bpm.  | User-selectable |
| <b>Afib</b>              | Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.   | User-selectable |

| Message                         | Cause   | Alarm level     |
|---------------------------------|---|-----------------|
| <b>Acc. Vent Rhythm</b>         | 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$ .  | User-selectable |
| <b>Pause</b>                    | No QRS is detected within the heartbeat pause threshold value that has been set.  | User-selectable |
| <b>Pause/min High</b>           | The measurement value of Pause/min is greater than high alarm limit that has been set.  | User-selectable |
| <b>PVCs High</b>                | The measurement value of PVCs is greater than high alarm limit that has been set.   | User-selectable |
| <b>VEB</b>                      | The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.  | User-selectable |
| <b>Multiform PVCs</b>           | Different forms of ventricular premature beats are detected in 15 beats.  | User-selectable |
| <b>IPVC</b>                     | The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.  | User-selectable |
| <b>PAC Bigeminy</b>             | The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).                          | User-selectable |
| <b>PAC Trigeminy</b>            | The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.  | User-selectable |
| <b>Low Voltage(Limb)</b>        | None of the signal amplitudes of I, II and III leads exceeds that of the alarm threshold that has been set.<br>PS: this alarm is available for 5 or 12 leads only, not available for 3 leads. | User-selectable |
| <b>RESP</b>                     |   |                 |
| <b>RESP No Breath</b>           | RESP waveform cannot be detected within the configured No Breath Detected delay time.   | High            |
| <b>RR High</b>                  | RR value is above the upper alarm limit.  | User-selectable |
| <b>RR Low</b>                   | RR value is below the lower alarm limit.  | User-selectable |
| <b>SpO<sub>2</sub></b>          |   |                 |
| <b>SpO<sub>2</sub> No Pulse</b> | The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor cannot detect the pulse signal.                                     | High            |
| <b>SpO<sub>2</sub> Desat</b>    | SpO <sub>2</sub> value is below the SpO <sub>2</sub> Desat Limit.   | High            |

| Message   | Cause   | Alarm level     |
|---|---|-----------------|
| <b>SpO<sub>2</sub> High</b>   | SpO <sub>2</sub> value is above the upper alarm limit.                                      | User-selectable |
| <b>SpO<sub>2</sub> Low</b>  | SpO <sub>2</sub> value is below the lower alarm limit.                                      | User-selectable |
| <b>PR</b>   |   |                 |
| <b>PR High</b>  | PR value is above the upper alarm limit.  | User-selectable |
| <b>PR Low</b>   | PR value is below the lower alarm limit.  | User-selectable |
| <b>TEMP</b>   |   |                 |
| <b>TEMP T1 High</b>   | Value of the T1 channel is above the upper alarm limit.                                     | User-selectable |
| <b>TEMP T1 Low</b>  | Value of the T1 channel is below the lower alarm limit.                                     | User-selectable |
| <b>TEMP T2 High</b>   | Value of the T2 channel is above the upper alarm limit.                                     | User-selectable |
| <b>TEMP T2 Low</b>  | Value of the T2 channel is below the lower alarm limit.                                     | User-selectable |
| <b>TEMP TD High</b>   | The temperature difference between the two channels is greater than the preset upper limit. | User-selectable |
| <b>NIBP</b>   |   |                 |
| <b>NIBP SYS High</b>  | SYS value is above the upper alarm limit.   | User-selectable |
| <b>NIBP SYS Low</b>   | SYS value is below the lower alarm limit.   | User-selectable |
| <b>NIBP DIA High</b>  | DIA value is above the upper alarm limit.   | User-selectable |
| <b>NIBP DIA Low</b>   | DIA value is below the lower alarm limit.   | User-selectable |
| <b>NIBP MAP High</b>  | MAP value is above the upper alarm limit.   | User-selectable |
| <b>NIBP MAP Low</b>   | MAP value is below the lower alarm limit.   | User-selectable |
| <b>IBP</b>  |   |                 |
| <b>YY SYS High</b><br>(YY stands for the IBP label name:<br>ART, Ao, UAP ,<br>BAP, FAP, LV,<br>P1-P4) | YY SYS value is above the upper alarm limit.  | User-selectable |
| <b>YY SYS Low</b><br>(YY stands for the IBP label name:<br>ART, Ao, UAP ,<br>BAP, FAP, LV,<br>P1-P4)  | YY SYS value is below the lower alarm limit.  | User-selectable |

| Message  | Cause  | Alarm level     |
|--|--|-----------------|
| <b>YY DIA High</b><br>(YY stands for the IBP label name: ART, Ao, UAP , BAP, FAP, LV, P1-P4) | YY DIA value is above the upper alarm limit. | User-selectable |
| <b>YY DIA Low</b><br>(YY stands for the IBP label name: ART, Ao, UAP , BAP, FAP, LV, P1-P4)  | YY DIA value is below the lower alarm limit. | User-selectable |
| <b>YY MAP High</b><br>(YY stands for the IBP label name: ART, Ao, UAP , BAP, FAP, LV, P1-P4) | YY MAP value is above the upper alarm limit. | User-selectable |
| <b>YY MAP Low</b><br>(YY stands for the IBP label name: ART, Ao, UAP , BAP, FAP, LV, P1-P4)  | YY MAP value is below the lower alarm limit. | User-selectable |
| <b>PA SYS High</b>   | PA SYS value is above the upper alarm limit. | User-selectable |
| <b>PA SYS Low</b>  | PA SYS value is below the lower alarm limit. | User-selectable |
| <b>PA DIA High</b>   | PA DIA value is above the upper alarm limit. | User-selectable |
| <b>PA DIA Low</b>  | PA DIA value is below the lower alarm limit. | User-selectable |
| <b>PA MAP High</b>   | PA MAP value is above the upper alarm limit. | User-selectable |
| <b>PA MAP Low</b>  | PA MAP value is below the lower alarm limit. | User-selectable |
| <b>YY MAP High</b><br>(YY stands for the IBP label name: CVP, ICP, LAP, RAP, UVP, P1-P4)     | YY MAP value is above the upper alarm limit. | User-selectable |

| Message   | Cause  | Alarm level     |
|---|--|-----------------|
| <b>YY MAP Low</b><br>(YY stands for the IBP label name: CVP, ICP, LAP, RAP, UVP, P1-P4) | YY MAP value is below the lower alarm limit.   | User-selectable |
| <b>CO<sub>2</sub></b>   |  |                 |
| <b>CO<sub>2</sub> No Breath Detected</b>  | Within the configured No Breath Detected alarm delay time, no RESP can be detected using CO <sub>2</sub> module. | High            |
| <b>etCO<sub>2</sub> High</b>  | etCO <sub>2</sub> value is above the upper alarm limit.  | User-selectable |
| <b>etCO<sub>2</sub> Low</b>   | etCO <sub>2</sub> value is below the lower alarm limit.  | User-selectable |
| <b>FiCO<sub>2</sub> High</b>  | FiCO <sub>2</sub> value is above the upper alarm limit.  | User-selectable |
| <b>C.O.</b>   |  |                 |
| <b>C.O. TB High</b>   | TB value is above the upper alarm limit.   | User-selectable |
| <b>C.O. TB Low</b>  | TB value is below the lower alarm limit.   | User-selectable |

## 6.2 Technical Alarm Information

| Message                 | Cause   | Alarm Level | Action Taken   |
|-------------------------|---|-------------|--|
| <b>ECG</b>              |   |             |  |
| <b>ECG Comm Fail</b>    | ECG module failure or communication failure.  | High        | Stop using measuring function of ECG module, and notify biomedical engineer or manufacturer's service staff. |
| <b>ECG HR Overrange</b> | HR value exceeds the measuring range ± accuracy.  | High        | 1. Check the patient type.<br>2. Check the ECG lead connection.  |
| <b>ECG Lead Off</b>     | 1) The drive electrode or more than one ECG limb electrode falls off the skin;<br>2) ECG cables fall off the monitor. | Low         | Confirm all electrodes, leads, and patient cables are properly connected.                                    |
| <b>ECG LL Lead Off</b>  | ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.  | Low         |  |

| Message                    | Cause  | Alarm Level | Action Taken  |
|----------------------------|--|-------------|---|
| <b>ECG LA Lead Off</b>     | ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.   | Low         |   |
| <b>ECG RA Lead Off</b>     | ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.   | Low         |   |
| <b>ECG RL Lead Off</b>     | When electrode type is AUTO, ECG electrode RL falls off the skin or the ECG cable RL falls off the monitor, the electrode type switches from 5/6/10 to 3 electrodes. | Low         |   |
| <b>ECG V Lead Off</b>      | ECG electrode V falls off the skin or the ECG cable V falls off the monitor.   | Low         |   |
| <b>ECG V1 Lead Off</b>     | ECG electrode V1 falls off the skin or the ECG cable V1 falls off.   | Low         |   |
| <b>ECG V2 Lead Off</b>     | ECG electrode V2 falls off the skin or the ECG cable V2 falls off.   | Low         |   |
| <b>ECG V3 Lead Off</b>     | ECG electrode V3 falls off the skin or the ECG cable V3 falls off.   | Low         | Make sure that all electrodes, leads and patient cables are properly connected. |
| <b>ECG V4 Lead Off</b>     | ECG electrode V4 falls off the skin or the ECG cable V4 falls off.   | Low         |   |
| <b>ECG V5 Lead Off</b>     | ECG electrode V5 falls off the skin or the ECG cable V5 falls off.   | Low         |   |
| <b>ECG V6 Lead Off</b>     | ECG electrode V6 falls off the skin or the ECG cable V6 falls off.   | Low         | Make sure that all electrodes, leads and patient cables are properly connected. |
| <b>ECG Signal Exceeded</b> | ECG measuring signal is beyond measuring range.  | Low         | Check lead connection and patient condition.                                    |

| Message                      | Cause  | Alarm Level | Action Taken   |
|------------------------------|--|-------------|--|
| <b>ECG Noise</b>             | ECG measuring signal is greatly interrupted.                                       | Low         | Check lead connection and patient condition.   |
| <b>RESP</b>                  |  |             |  |
| <b>RESP Comm Fail</b>        | RESP module failure or communication failure                                       | High        | Stop using measuring function of RESP module, and notify biomedical engineer or the manufacturer's service staff.  |
| <b>RESP Cardiac Artifact</b> | No RESP waveform can be detected due to apnea or shallow breathing of the patient. | High        | Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact. |
| <b>RESP RR Exceed</b>        | RR measuring value is out of the measure range.                                    | Medium      | Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger the patient life.   |

| Message                              | Cause   | Alarm Level     | Action Taken   |
|--------------------------------------|---|-----------------|--|
| <b>RESP Noise</b>                    | RR cannot be measured due to patient movement.  | Low             | Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.  |
| <b>SpO<sub>2</sub></b>               |   |                 |  |
| <b>SpO<sub>2</sub> Comm Fail</b>     | SpO <sub>2</sub> module failure or communication failure  | High            | Stop using measuring function of SpO <sub>2</sub> module, and notify biomedical engineer or manufacturer's service staff.                                    |
| <b>SpO<sub>2</sub> Sensor Off</b>    | SpO <sub>2</sub> sensor may be disconnected from the patient measuring site.  | User-selectable | Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.                          |
| <b>SpO<sub>2</sub> Sensor Err</b>    | Malfunction in the SpO <sub>2</sub> sensor or in the extension cable.   | Low             | Replace the SpO <sub>2</sub> sensor or the extension cable.  |
| <b>SpO<sub>2</sub> No Sensor</b>     | No SpO <sub>2</sub> sensor was connected to the monitor.  | User-selectable | Make sure the monitor and sensor are well connected, reconnect the sensor.   |
| <b>SpO<sub>2</sub> Low Perfusion</b> | The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO <sub>2</sub> value and PR value might be inaccurate then. | Low             | Reconnect the SpO <sub>2</sub> sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff. |

| Message   | Cause  | Alarm Level | Action Taken   |
|---|--|-------------|--|
| <b>SpO<sub>2</sub> Noisy Signal</b>   | There is interference with SpO <sub>2</sub> measurement signals due to patient movement, ambient light, electrical interference or else. | Low         | Check the condition of patient and avoid patient movement; make sure the cable is well connected.  |
| <b>SpO<sub>2</sub> Light Interference</b>   | Ambient light around the sensor is too strong.   | Low         | Reduce interference of the ambient light and avoid sensor's exposure to strong light.  |
| <b>NOTE: Before the measurement, the SpO<sub>2</sub> No Sensor/SpO<sub>2</sub> Sensor Off is indicated as a prompt information.</b> |  |             |  |
| <b>NIBP</b>   |  |             |  |
| <b>NIBP Comm Fail</b>   | NIBP module failure or communication failure   | High        | Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.                                    |
| <b>NIBP Aux Excessive Pressure</b>  | Pressure has exceeded the second safety limit as specified.  | High        | Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff. |
| <b>NIBP Self Test Error</b>   | Sensor or other hardware errors.   | High        | Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff. |
| <b>NIBP System Failure</b>  | NIBP is not calibrated.  | High        | Contact your service personnel.  |
| <b>NIBP Range Exceeded</b>  | All of the SYS, DIA and MAP value are beyond the measurement range.  | High        |  |

|                                |  |      |  |
|--------------------------------|--|------|--|
| <b>SYS(NIBP) Overrange</b>     | SYS (NIBP) value is beyond the measurement range.          | High | Use other methods to measure blood pressure.   |
| <b>DIA(NIBP) Overrange</b>     | DIA (NIBP) value is beyond the measurement range.          | High |  |
| <b>MAP(NIBP) Overrange</b>     | MAP (NIBP) value is beyond the measurement range.          | High |  |
| <b>NIBP Leak</b>               | NIBP pump, valve, cuff or tube has a leakage.              | Low  | Check the connections and the wrapped cuff to see whether they are all prepared well.<br>If failure persists, please notify biomedical engineer or manufacturer's service staff. |
| <b>NIBP Over Pressure</b>      | Pressure has exceeded the specified upper safety limit.    | Low  | Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.                                 |
| <b>NIBP Init Pressure High</b> | The initial pressure is too high during measuring          | Low  | Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.                                 |
| <b>NIBP Time Out</b>           | Measuring time has exceeded the specified time.            | Low  | Measure again or use other measuring method.   |
| <b>NIBP Cuff Type Error</b>    | The cuff type used isn't consistent with the patient type. | Low  | Confirm the patient type and change the cuff.  |

| Message                                 | Cause   | Alarm Level | Action Taken   |
|---|---|-------------|--|
| <b>NIBP Airway Pressure Abnormality</b> | Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed. | Low         | Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel. |
| <b>NIBP Weak Signal</b>                 | Cuff is too loose or patient pulse is too weak.   | Low         | Use other methods to measure blood pressure.   |
| <b>NIBP Loose Cuff</b>                  | Cuff is not properly wrapped or no cuff is connected.   | Low         | Properly wrap the cuff.  |
| <b>NIBP Interference</b>                | Signal noise is too large or pulse rate is not regular due to the patient movement.                     | Low         | Make sure that the patient under monitoring is motionless.   |
| <b>NIBP Leak Test Error</b>             | Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.                    | Low         | Test again. If the problem still exists, contact your service personnel.   |
| <b>TEMP</b>                             |   |             |  |
| <b>TEMP Comm Fail</b>                   | TEMP module failure or communication failure.   | High        | Stop using measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.                        |
| <b>Excessive T1</b>                     | TEMP1 value is beyond measuring range.  | High        | Check sensor connection and patient condition.   |
| <b>Excessive T2</b>                     | TEMP2 value is beyond measuring range.  | High        | Check sensor connection and patient condition.   |

| Message                      | Cause   | Alarm Level | Action Taken   |
|------------------------------|---|-------------|--|
| <b>T1 Calibration Failed</b> | T1 calibration failed.  | High        | Please check whether the module works properly.  |
| <b>T2 Calibration Failed</b> | T2 calibration failed   | High        | Please check whether the module works properly.  |
| <b>TEMP T1 Sensor Off</b>    | Temperature cable of TEMP channel 1 may be disconnected from the monitor.                   | Low         | Make sure that the cable is properly connected.  |
| <b>TEMP T2 Sensor Off</b>    | Temperature cable of TEMP channel 2 may be disconnected from the monitor.                   | Low         | Make sure that the cable is properly connected.  |
| <b>IBP</b>                   |   |             |  |
| <b>YY Comm Fail</b>          | IBP module failure or communication failure   | High        | Stop using measuring function of IBP module, and notify biomedical engineer or manufacturer's service staff.   |
| <b>YY Disconnected</b>       | The liquid way is disconnected from the patient, or the three-way valve is open to the air. | High        | Check the connection of the liquid way, or check the valve is open to the patient. If the problem persists, notify the manufacturer's service staff. |
| <b>YY No Pulse</b>           | The pulse signal is too weak for the monitor to analyze.                                    | High        | PR value is beyond the measurement range. Please check the patient status.   |

| Message  | Cause  | Alarm Level  | Action Taken  |
|--|--|--|---|
| <b>YY Sensor Off</b>                           | IBP sensor falls off.                                    | Medium<br>(It is indicated as a prompt information before the measurement) | Check the sensor connection and reconnect the sensor.   |
| <b>YY Sensor Err</b>                           | Malfunction in the IBP sensor or in the extension cable. | Medium   | Replace the IBP sensor or the extension cable.  |
| <b>Abnormal YY Power</b>                       | Malfunction in the IBP power                             | Medium   | Stop using measuring function of IBP module, and notify biomedical engineer or manufacturer's service staff.  |
| <b>YY Alias Conflict</b>                       | IBP alias has conflict.                                  | Medium   | Choose another label among the options from the Alias pull-down list to resolve the label conflict.   |
| <b>YY-S Overrange</b>                          | SYS (YY) value is beyond the measurement range.          | Low  | Make sure that the measurement has been properly prepared and zeroed, and that the transducer is level with the heart. If the problem persists, try another transducer. |
| <b>YY-D Overrange</b>                          | DIA (YY) value is beyond the measurement range.          | Low  |   |
| <b>YY-M Overrange</b>                          | MAP (YY) value is beyond the measurement range.          | Low  |   |
| <b>YY PR Overrange</b>                         | PR (YY) value is beyond the measurement range.           | Low  |   |
| <b>NOTE: YY stands for the IBP label name.</b> |  |  |   |

| Message  | Cause   | Alarm Level | Action Taken   |
|--|---|-------------|--|
| <b>C.O.</b>                                      |   |             |  |
| <b>C.O. Comm Fail</b>                            | C.O. module failure or communication failure  | High        | Stop using measuring function of C.O. module, or notify biomedical engineer or manufacturer's service staff. |
| <b>TI TEMP Out Of Range</b>                      | TI value is beyond measuring range.   | High        | Please check TI sensor.  |
| <b>TB TEMP Out Of Range</b>                      | TB value is beyond measuring range.   | High        | Please check TB sensor.  |
| <b>C.O. TI Sensor Off</b>                        | C.O. TI sensor not connected.   | Low         | Insert injective temperature sensor.   |
| <b>C.O. TB Sensor Off</b>                        | C.O. TB sensor not connected.   | Low         | Insert TB sensor.  |
| <b>CO<sub>2</sub></b>                            |   |             |  |
| <b>CO<sub>2</sub> Comm Fail</b>                  | CO <sub>2</sub> module communication failure  | High        | Stop using measuring function of CO <sub>2</sub> module, notify biomedical engineer.                         |
| <b>CO<sub>2</sub> Module Error</b>               | CO <sub>2</sub> module failure  | High        |  |
| <b>CO<sub>2</sub> Sensor TEMP Overrange</b>      | The temperature of the CO <sub>2</sub> module exceeds the operating temperature range | High        |  |
| <b>CO<sub>2</sub> etCO<sub>2</sub> Overrange</b> | The etCO <sub>2</sub> concentration exceeds the measurement range.                    | High        |  |
| <b>CO<sub>2</sub> FiCO<sub>2</sub> Overrange</b> | The FiCO <sub>2</sub> concentration exceeds the measurement range.                    | High        |  |
| <b>Watertrap is full</b>                         | Water trap of the sidestream module is full.  | High        | Replace the water trap.  |

| Message                               | Cause  | Alarm Level | Action Taken  |
|---------------------------------------|--|-------------|---|
| <b>CO<sub>2</sub> Watertrap Check</b> | The water trap is disconnected or not properly connected.                                  | Low         | Properly connect the water trap.  |
| <b>CO<sub>2</sub> Noisy Signal</b>    | The CO <sub>2</sub> signal is interfered by ambient or electromagnetic interference        | Low         | Check interference sources around the device.   |
| <b>Others</b>                         |  |             |   |
| <b>Audio Failed</b>                   | Audio circuit connection is abnormal, or loudspeaker falls off.                            | High        | Stop using the monitor and notify the manufacturer's service staff.   |
| <b>Network Traffic Abnormity</b>      | Abnormal network traffic has been detected. The data traffic exceeds the limit.            | High        | Disconnect the network to make the monitor work properly, and then contact the professionals authorized by manufacturer to check the network problem. |
| <b>Data Disconnected</b>              | The system client is disconnected from the internal data service.                          | High        | Restart the monitor.  |
| <b>Battery Low</b>                    | Battery power lower than 3%, and the monitor will shut down automatically after 5 minutes. | High        | Please change the battery or charge the battery.  |
|                                       | Battery power lower than 25%, and the monitor can work for at least 20 minutes.            | Medium      |   |

| Message                                | Cause                                     | Alarm Level | Action Taken  |
|--|---|-------------|---|
| <b>Server Disconnected</b>             | The monitor's network is disconnected.    | Medium      | 1) Check if the network cable is well connected or Wi-Fi is connected.<br>2) Check if the central monitoring system is turned ON.<br>3) Check if the IP of bedside monitor and central monitoring system are on the same network segment. |
| <b>Gateway Disconnected</b>            | The monitor is disconnected with Gateway. | Medium      | Check network connection and check IP settings.   |
| <b>Battery Error</b>                   | Malfunction in Battery                    | Low         | Replace the battery and restart the monitor. If the problem persists, notify the manufacturer's service staff.  |
| <b>Battery Charge Voltage Too High</b> | Battery over-voltage during charging      | Low         | Stop using the battery and notify the manufacturer's service staff.   |
| <b>Recorder Out Of Paper</b>           | Recorder Out Of Paper                     | Low         | Please install the paper  |
| <b>Recorder Probe Overheated</b>       | The probe of recorder is overheated.      | Low         | Stop recording and retry after the probe cools.   |

|                             |   |     |  |
|-----------------------------|---|-----|--|
| <b>Recorder Voltage Low</b> | The monitor is battery low and does not support recording function. | Low | Ensure the monitor has adequate power. |
|-----------------------------|---|-----|--|

## 6.3 Prompts

| Message  | Cause   |
|--|---|
| <b>ARR Relearning</b>                              | The QRS template building required for Arr. Analysis is in process.   |
| <b>Unable to analyze QT</b>                        | QT algorithm cannot generate valid QT for more than 10 minutes (or 1 minute during startup).  |
| <b>Unable to analyze ST</b>                        | The ST algorithm cannot produce valid ST value, which may be caused by the large change in the measured value of connected cardiogram ST or ventricular pacing.             |
| <b>QT Baseline Overrange</b>                       | After modifying the calculation formula, the QTc parameter value exceeds the range.   |
| <b>Unable to analyze ECG</b>                       | The arrhythmia algorithm cannot analyze ECG data reliably.  |
| <b>ECG V-Fib/V-Tach Off</b>                        | V-Fib/V-Tach alarm is set to OFF.   |
| <b>ECG ExtremeTachy Off</b>                        | Extreme Tachycardia alarm is set to OFF.  |
| <b>ECG ExtremeBrady Off</b>                        | Extreme Bradycardia alarm is set to OFF.  |
| <b>ECG V-Tach Off</b>                              | V-Tach alarm is set to OFF.   |
| <b>ECG Vent Brady Off</b>                          | Vent Brady alarm is set to OFF.   |
| <b>Please check if the patient has a pacemaker</b> | When Pace is set to Unknown and pace pulse is detected.   |
| <b>Electrodes Contact Poor</b>                     | The electrode has bad contact with patient's body.  |
| <b>SpO<sub>2</sub> Searching Pulse</b>             | SpO <sub>2</sub> module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.                       |
| <b>Please Start Measure</b>                        | NIBP module is in idle status.  |
| <b>Measuring</b>                                   | The NIBP measurement is in process.   |
| <b>Done</b>  | NIBP measurement is completed.  |
| <b>Measurem. Canceled</b>                          | Press the "start/stop NIBP measurement" button or shortcut key  to stop the measurement. |

| Message                                     | Cause   |
|---|---|
| <b>Calibrating</b>                          | Monitor is currently calibrating.   |
| <b>Calibration Cancelled</b>                | Calibration is cancelled.   |
| <b>Main Sensor Calibration</b>              | Main sensor calibration is completed.   |
| <b>OPU Calibration Done</b>                 | OPU (Overpressure protection unit) calibration is completed.  |
| <b>Leak. Test Running</b>                   | The leakage test is in process.   |
| <b>Leak.Test Canceled</b>                   | Pneumatic test over.  |
| <b>Leakage Test Ok</b>                      | There is no leak.   |
| <b>Manometer Mode</b>                       | Calibrate in this mode.   |
| <b>ManualReset</b>                          | NIBP module in resetting.   |
| <b>STAT Aborted</b>                         | STAT measurement ends.  |
| <b>STAT Completed</b>                       | STAT is completed.  |
| <b>CO<sub>2</sub> Standby</b>               | Turn from measuring mode to standby mode, making the module in energy-saving status.                  |
| <b>CO<sub>2</sub> Sensor Warms Up</b>       | The CO <sub>2</sub> module is in warm-up state.   |
| <b>CO<sub>2</sub> Zeroing...</b>            | The zeroing of CO <sub>2</sub> module is in progress.   |
| <b>CO<sub>2</sub> Zero Success</b>          | CO <sub>2</sub> module completes zero calibration.  |
| <b>CO<sub>2</sub> Zero Failed</b>           | CO <sub>2</sub> module failed to complete the zero calibration.                                       |
| <b>CO<sub>2</sub> Zero Required Again</b>   | CO <sub>2</sub> module failed to complete the zero calibration.                                       |
| <b>Calibration OK</b>                       | Calibration is completed.   |
| <b>Calibration Failed</b>                   | Calibration is failed.  |
| <b>CO<sub>2</sub> Auto-zero Suppression</b> | CO <sub>2</sub> is in a state of automatic zero suppression.  |
| <b>CO<sub>2</sub> Zero Recovery</b>         | CO <sub>2</sub> is in the state of zero recovery.   |
| <b>YY Zero Required</b>                     | The pressure channel needs a valid zero. After the user performs zeroing, the information disappears. |
| <b>YY Searching Pulse</b>                   | Searching for a pulse.  |
| <b>Zero Success</b>                         | IBP completes zeroing.  |
| <b>Pressure Pulsating, Unable to Zero</b>   | During the zeroing process, pressure fluctuation is excessive.  |
| <b>Pressure Overrange, Unable to Zero</b>   | During the zeroing process, pressure value is beyond the zeroing range.                               |
| <b>Sensor Off, Unable to Zero</b>           | Perform zeroing when the sensor is off.   |
| <b>Invalid Time, Zero Failed.</b>           | Time is not set up prior zeroing.   |
| <b>Unable to Zero in Demo Mode</b>          | Perform zeroing in Demo Mode.   |

|   |   |
|---|---|
| <b>Zero In Progress</b>                           | Zeroing is in progress.   |
| <b>Pressure Pulsating, Unable to Calibrate</b>    | During the Calibration process, pressure fluctuation is excessive.  |
| <b>Pressure Overrange, Unable to Calibrate</b>    | During the Calibration process, pressure value is beyond the Calibration range.   |
| <b>Not Zeroed, Unable to Calibrate</b>            | Zeroing is not performed prior calibration.   |
| <b>Sensor Off, Unable to Calibrate</b>            | Perform calibration when the sensor is off.   |
| <b>Invalid Time, Calibration Failed.</b>          | Time is not set up prior calibration.   |
| <b>Unable to Calibrate in Demo</b>                | Perform calibration in Demo Mode.   |
| <b>C.O. Lack Param</b>                            | Parameter is not configured for C.O. measurement.   |
| <b>C.O. TI Sensor Off</b>                         | C.O. TI sensor off or disconnected before obtaining valid value.  |
| <b>C.O. TB Sensor Off</b>                         | C.O. TB sensor off or disconnected before obtaining valid value.  |
| <b>Measuring...</b>                               | C.O. measurement is in progress.  |
| <b>C.O. Measurement Cancelled</b>                 | Cancel this C.O. measurement.   |
| <b>Invalid Measurement</b>                        | During the measurement process, unplug the sensor, temperature overrange, and so forth.                                   |
| <b>Measurement Completed</b>                      | C.O. measurement is completed.  |
| <b>TEMP Overrange</b>                             | The temperature is out of range and C.O. cannot be measured.  |
| <b>No Sensor, unable to measure!</b>              | C.O. No sensor.   |
| <b>Lack of parameter, unable to score</b>         | In Warning-Score System interface, parameters are not completely input.   |
| <b>NIBP Simul</b>                                 | NIBP Simul function is turned on.   |
| <b>More than 5 consecutive password</b>           | Continuously enter the wrong password for more than 5 times.  |
| <b>Export Failed</b>                              | Failed to export the trend table data to the USB flash drive.   |
| <b>Export Success</b>                             | The trend table data export is completed.   |
| <b>Space Limited, circular storage will start</b> | The storage space is less than 260 M. The circular storage is about to start.   |
| <b>Deleting data during circular storage</b>      | The storage space is less than 250 M. The circular storage is in progress and earlier data will be replaced by later one. |

|   |  |
|---|--|
| <b>Automatically adjust alarm limits?</b> | The monitor pop-up prompt when clicking auto alarm limit button.                           |
| <b>Patient quantity exceeds limit</b>     | In the ADT query interface, the patients that meet the query conditions exceeds the limit. |

## 6.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

| Parameter | Patient Type      | Adjustable Range |
|-----------|-------------------|------------------|
| HR        | Adult             | 15~300           |
|           | Pediatric/Neonate | 15~350           |

ST analysis alarm limits are listed as follows: unit (mV)

| Parameter | Adjustable Range |
|-----------|------------------|
| ST        | -2.00~2.00       |

QTc and ΔQTc alarm limits are listed as follows: unit (ms)

| Parameter | Adjustable Range |
|-----------|------------------|
| QTc       | 200~800          |
| ΔQTc      | 30~200           |

RESP alarm limits are listed as follows: unit (rpm)

| Parameter | Adjustable Range |
|-----------|------------------|
| RR        | 0~200            |

SpO<sub>2</sub> alarm limits are listed as follows: unit (%)

| Parameter        | Adjustable Range |
|------------------|------------------|
| SpO <sub>2</sub> | 20~100           |

SpO<sub>2</sub> Desat Limits are listed as follows: unit (%)

|                              | Adjustable Range |
|------------------------------|------------------|
| SpO <sub>2</sub> Desat Limit | 20~99            |

**NOTE: User can set the range through User Maintain > Alarm Setup > SpO<sub>2</sub> Desat Limit, SpO<sub>2</sub> Desat Limit should be less than or equal to SpO<sub>2</sub> alarm low limit. When the SpO<sub>2</sub> measurement falls below the SpO<sub>2</sub> Desat threshold, the monitor will trigger the "SpO<sub>2</sub> Desat" alarm.**

PR alarm limits are listed as follows: unit (bpm)

| Parameter | Adjustable Range |
|-----------|------------------|
| PR        | 30~300           |

NIBP alarm limits are listed as follows: unit (mmHg)

| Patient Type | Parameter | Adjustable Range |
|--------------|-----------|------------------|
| Adult        | SYS       | 25~290           |
|              | DIA       | 10~250           |
|              | MAP       | 15~260           |
| Pediatric    | SYS       | 25~240           |
|              | DIA       | 10~200           |
|              | MAP       | 15~215           |
| Neonate      | SYS       | 25~140           |
|              | DIA       | 10~115           |
|              | MAP       | 15~125           |

TEMP alarm limits are listed as follows:

| Parameter | Adjustable Range                          |
|-----------|---|
| T1        | 0 °C (32 °F)~50 °C (122 °F)               |
| T2        | 0 °C (32 °F)~50 °C (122 °F)               |
| TD        | High limit: 0.1 °C (0.2 °F)~50 °C (90 °F) |

IBP alarm limits are listed as follows: unit (mmHg)

| Parameter | Adjustable Range |
|-----------|------------------|
| IBP       | -50~360          |

CO<sub>2</sub> alarm limits are listed as follows:

| Parameter         | Adjustable Range           |
|-------------------|----------------------------|
| etCO <sub>2</sub> | 0 mmHg~152 mmHg            |
| FiCO <sub>2</sub> | High limit: 0 mmHg~50 mmHg |
| AwRR              | 0 rpm~150 rpm              |

C.O. alarm limits are listed as follows:

| Parameter | Adjustable Range                 |
|-----------|----------------------------------|
| TB        | 23 °C (73.4 °F)~43 °C (109.4 °F) |

# Chapter 7 Managing Patients

## 7.1 Confirming a Patient

**NOTE: If the user does not make a selection within 1 minute, Current Patient is selected by default.**

When the monitor is powered ON, the message Continue monitoring the current patient or admit a new patient? is displayed if the patient was not discharged from the monitor before it was powered OFF. Select **Current Patient** to use the current configuration or select **New Patient** to admit new patient.

## 7.2 Discharging a Patient

Always discharge the previous patient before monitoring a new patient. Failure to do so can lead to data being attributed to the wrong patient.

To discharge a patient:

1. Select any of these methods to access the **Discharge** page:

- Select the shortcut key .
- Select **Menu > Patient Setup > Patient Info > Discharge**.
- Select the patient information area and select **Discharge**.

2. Select an option in the **Discharge** dialog:

- **Standby after Discharge:** After discharging the patient, the monitor enters standby mode.
- **New Patient:** After discharging the current patient, the monitor displays the patient admission screen.
- **Cancel:** Cancel the patient discharge.

After discharging the patient, all patient data, including patient information, trend data, and physiological alarm information, is cleared and the technical alarm status is reset.

## 7.3 Admitting a Patient

**NOTE:**

- 1 Creating new patient and updating a patient will clear the history data in the monitor associated with the patient.
- 2 For the Bed Label field, English or Chinese can be selected by switching the keyboard language and select special characters using .

The monitor displays physiological data and stores it in the data trends as soon as a

patient is connected to the monitor. The patient can then be monitored even though they are not yet admitted. Patients must be admitted properly so they can be identified on reports and networked devices.

During patient admission, the monitor requires specific data for safe and accurate operation. This data includes:

- The patient category setting (determines the algorithm the monitor uses to process and calculate certain measurements).
- The safety limits used for certain measurements.
- The alarm limit ranges.

To admit a patient, please:

1. Select the patient information area or select **Menu > Patient Setup > Patient Info** to enter the patient information page.
2. Enter the patient information:
  - **Patient ID:** Enter the patient's medical record number.
  - **Bed Label:** Enter the bed label (up to 20 characters). Chinese, English, numbers, and special characters can be entered. To control the permission to change the Bed Label, enable Bed Label Lock in User Maintain > Patient Setup menu, and thus password is required to modify the bed label.
  - **Last Name:** Enter the patient's last name (family name).
  - **First Name:** Enter the patient's first name.
  - **Age:** Enter the patient's age.
  - **Date of Birth:** Enter the patient's date of birth.
  - **Date of Admission:** Enter the patient's date of admission.
  - **Type:** Choose the patient type, either Adult, Pediat, or Neonate.
  - **Blood Type:** Choose N/A, A, B, AB, and O.
  - **Pace:** Choose ON, OFF, or Unknown (ON must be selected if the patient has a pacemaker).
  - **Gender:** Choose Male, Female, or N/A.
  - **Height:** Enter the patient's height (cm or in).
  - **Weight:** Enter the patient's weight (kg or lb).
  - **BMI:** The system calculates the BMI automatically based on the height and weight values.
  - **TEMP:** Enter the patient's temperature.
  - **Department:** Enter the patient's department.

- **Doctor:** Enter the patient's attending doctor.
- **Nurse:** Enter the patient's nurse in charge.

The patient information to be displayed can be set in **Menu > System > User Maintain > Patient Setup**. The Patient ID, Bed Label, Last Name, First Name, Type and Pace are fixed display items and cannot be hidden.

3. Click Confirm to admit the patient.

### 7.3.1 Patient Category and Pace Status

#### **WARNING**

- 1 Changing the patient category may change the arrhythmia and NIBP alarm limits. The alarm limits must always be appropriate for the patient.
- 2 The Pace must be set to ON for patients with a pacemaker. If it is set to OFF, the monitor could mistake a pace pulse for a QRS and fail to give an alarm during asystole.

The patient category setting determines the algorithm the monitor uses to process and calculate certain measurements, the safety limits applied for certain measurements, and the alarm limit ranges.

The pace setting determines if the monitor shows pace pulse marker.

### 7.4 Quick Admit

Quick Admit can be used to quickly admit a patient and complete the rest of the patient information later. To quickly admit a patient:

1. Select the shortcut key .
2. Configure **Type** and **Pace** information.
3. Select **Confirm** to continue or **Cancel** to go back.

### 7.5 Barcode Admit

The barcode scanner can recognize patient information quickly for convenience and to reduce user error.

Scan the patient barcode/QR code with the scanner.

- If the monitor is connected with ADT server through Gateway, the monitor will automatically inquire for patient information from ADT server via patient ID. As soon as the patient ID is successfully found, the corresponding patient information will be updated on the monitor. Otherwise, prompt information will be displayed to notify that network is not available or no patient

information is matched. If patient information is modified on ADT server, prompt information will also be sent to inform of the update.

- If the patient ID is the same as the current patient, the Patient Info screen is displayed and the patient information is updated with the barcode information. Select Confirm to keep the updated information.
- If the patient ID is different from the current patient, the Admission screen is displayed and the patient information is updated with the barcode information. Edit the patient information as needed. Select Confirm to admit the patient.

The patient information is updated with the barcode information according to the barcode setup. The patient information will always be transferred in HL7 protocol. The monitor transfers the updated patient information to the EMR system once the patient information is changed.

## 7.6 Managing Patient Information

### 7.6.1 Editing Patient Information

**NOTE: When changing the patient type, the patient will be readmitted as a new patient.**

To edit the patient information after a patient has been admitted:

1. Select **Menu > Patient Setup > Patient Info.**
2. Edit the patient information.
3. Select **Confirm.**

If the monitor has a barcode scanner, the patient's barcode can be scanned to enter patient information.

### 7.6.2 Loading Patient information from ADT Server

**NOTE: Load patient information from the network server only when ADT Query is set to ON. For more information, see SectionUsingADTQuery.**

If the monitor is connected with Admit-Discharge-Transfer (ADT) server through Gateway. The user can obtain patient information from ADT server to the monitor.

To obtain patient information from ADT server,

1. Select **Menu > Patient Setup > Network Query.**
2. Input the query conditions, and then click **Query**. A list including all the patients that meet the query conditions is displayed.
3. Select a patient from the patient list, and click **Admit**. The corresponding patient information in the monitor will be updated after confirmation.

## Chapter 8 Managing Profiles

Profiles are predefined monitor configurations. The monitor configurations can be changed to adapt to different monitoring situations. Different sets of profiles can be configured to accommodate various patient types and departments.

### 8.1 Changing Institutional Default Profile

The monitor will load the pre-set institutional default profile when a patient is admitted or the patient type is changed. To change the institutional default profile:

1. Select Menu > Profile > Institutional Defaults.
2. Select a profile from the pop-up list.
3. Enter the password to confirm the selection. This profile can be either a factory default profile or a saved user profile.

### 8.2 Resetting to Factory Default Profile

To set the factory default profile, select Menu > Profile > Profile Management and choose a factory profile (adult, pediatric or neonate).

### 8.3 Setting User Profile

NOTE: The profile currently in use cannot be deleted.

Up to 25 user profiles can be saved in the monitor. The  symbol marks the current profile. To set the user profile:



Select the shortcut key  or select Menu > Profile > Profile Management > User Profile:

- **Apply:** Apply the currently selected profile.
- **Save and Apply:** Enter the password and profile name. Select Confirm to save and apply the current settings.
- **Delete:** Enter the password to delete the currently selected profile.

### 8.4 Transferring Profile

When installing several monitors with identical user profiles, it is not necessary to set up a profile for each monitor. A USB flash drive can be used to transfer the same profile to monitors.

To export the current monitor's profile:

1. Connect the USB flash drive to a monitor USB port.
2. Select Menu > Profile > Transfer Profile and enter the password.
3. Choose the removable device.
4. Select Export.
5. Select a profile from the profile list.
6. Select Confirm.

To transfer the profile from the USB flash drive to the monitor:

1. Connect the USB flash drive to the monitor USB port.
2. Select Menu > Profile > Transfer Profile and enter the password.
3. Choose the removable device.
4. Select Import.
5. Select the profile from the list.
6. Select Confirm.

# Chapter 9 User Interface

## 9.1 Parameters ON or OFF

**NOTE: When a parameter is manually set to OFF, the corresponding parameter module stops working and the parameter cannot be displayed in the main menu.**

Parameters can be set to ON or OFF based on the requirement.



1. Select the shortcut key  on the screen or select Menu > Parameter > Param Switch.
2. Touch the parameter switch to set to ON or OFF. Select Param Setup to access the setup menu of the specific enabled parameter.

## 9.2 Changing Screen Layout

To change the screen layout:

Select Menu > Screen to open the setup menu which contains the following options:

- Select the desired screen based on the clinical needs in Screen Setup or select the shortcut key  to change the screen layout.
- On the Parameter Layout page:
  - Select Add Row/Add Column or Remove Row/Remove Column to set the number of rows and columns.
  - Select a specified parameter or waveform area and choose the elements to be displayed. All Parameters can be enabled to show all the parameters on the screen. Click  to clear the parameter selection.
  - Select  or  to merge or split the parameter area.
  - Select  or  to change the parameter or waveform area.
  - Enable Auto Layout to adjust the layout automatically.
- Select the required shortcut keys and adjust the sequence by dragging any key on the Shortcut Keys page (password protected).
- Set the screen brightness on the Display Setup page. See SectionAdjusting ScreenBrightnessfor details.
- Select Night mode on the Night Mode Setup page. See SectionNightMode for details.

## 9.3 Standard Screen

The standard screen is most frequently used for patient monitoring. To enter the standard screen, select Menu > Screen > Screen Setup > Standard. See Section OperatingandNavigatingfor the standard screen layout.

## 9.4 Large Font Screen

The large font screen displays parameter values in a larger font size. To enter the large font screen:

1. Select Menu > Screen > Screen Setup > Large Font.
2. Select Menu > Screen > Parameter Layout to choose the elements to be displayed.

## 9.5 Trend Screen

The trend screen shows the recent graphic trends of parameters. To enter the trend screen:

1. Select Menu > Screen > Screen Setup > Trend Screen.
2. Select a short trend to open the Short Trend Setup menu. Set Time Interval for the trend.

## 9.6 OxyCRG Screen

The OxyCRG screen is always used in the NICU because neonate SpO<sub>2</sub>, HR and Resp are different than adults. The OxyCRG screen includes HR trend, SpO<sub>2</sub> trend, and RR trend or RESP compressed waveform. To enter the OxyCRG screen:

1. Select Menu > Screen > Screen Setup > OxyCRG.
2. Select an OxyCRG waveform to open OxyCRG Setup menu and set:
  - Time Interval: set the trend time and compressed waveform time.
  - RESP Display: select RR for RR trend or RESP for RESP compressed waveform.

## 9.7 ECG Screen

When Electrode Type is 5 Electrodes or 6 Electrodes, Screen Setup can be set to Full-Screen and Half-Screen; When Electrode Type is 10 Electrodes, Screen Setup can be set to Full-Screen.

- Full-Screen:
  - For 5 electrodes, display seven ECG waveforms which occupy the area of seven waveforms on the main screen.

- For 6 electrodes, display eight ECG waveforms which occupy the area of eight waveforms on the main screen.
- For 10 electrodes, display 12 ECG waveforms which occupy the area of six waveforms on the main screen.
- Half-Screen:
  - For 5 electrodes, display seven ECG waveforms which occupy the area of four waveforms on the main screen.
  - For 6 electrodes, display eight ECG waveforms which occupy the area of four waveforms on the main screen.

## 9.8 Changing Parameter and Waveform Colors

The parameter and waveform display colors can be set as desired. To change the display color, select Menu > Screen > Color Setup > Current or All.

## 9.9 Changing Waveform Line Thickness

To change the waveform line thickness:

1. Select Menu > System > User Maintain and enter the password.
2. Select Other Setups > Wave Line.
3. Select Thick, Medium, or Thin.

## 9.10 Changing Waveform Scale Plotting

To change the plotting of waveform scale:

1. Select Menu > System > User Maintain and enter the password.
2. Select Other Setups > Scale Plotting.
3. Select Line or Point.

## 9.11 Displaying the Timer

NOTE:

- 1 Timer settings cannot be changed when a timer is running.
- 2 Do not use the timer to schedule critical patient-related tasks.

The monitor has the timer function to notify when a preset time period is expired. To display the timer on the main screen:

1. Select Menu > Screen > Parameter Layout.
2. Select the parameter area and select Timer 1/Timer 2/Timer 3/Timer 4 from the popup interface. Exit the menu and the screen will adjust the parameters automatically.

Click the timer area to access the timer setup menu.

- Set Timer Type:
  - Normal: The timer has a predefined timing duration, and stops when the run time is reached.
  - Cycled: The timer has a predefined timing duration. When the timing duration is reached, the timer restarts automatically. The cycles are also displayed.
  - Clock: The timer displays the system time.
- Set Timing Direction.
  - Count Down: to display the remaining time. When selecting Count Down, Timing Duration shall be set simultaneously. When the remaining time is 10 s, the time turns red, prompting that the timing duration is to expire. When the timing duration expires, the monitor issues a reminder tone.
  - Count Up: to display the elapsed time.
- Set Reminder Volume.

The timer provides the following controls:

- Start: starts the timer.
- Pause: pauses the timer.
- Continue: continues the timing.
- Reset: clears the timer and end this timer episode.

# Chapter 10 Monitoring ECG

## 10.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays ECG waveform and ECG value on the monitor. ECG monitoring provides 3-lead, 5-lead, 6-lead, and 12-lead ECG monitoring, arrhythmia analysis, ST-segment analysis, and QT/QTc measurements.

## 10.2 ECG Safety Information

### **WARNING**

- 1 Store the electrodes in room temperature. Use the electrodes as soon as possible after opening the electrode package. Never mix electrode types or brands, this may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.
- 2 Place the electrode carefully and ensure a good contact. Inspect the electrodes application sites every day to ensure skin integrity. If the skin quality changes, replace the electrodes every 24 hours or change the application site.
- 3 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the alarm of “ECG LEAD OFF” and the audible alarm is activated.
- 4 When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device; otherwise, there will be a great deal of interference with the ECG signal.
- 5 The electrodes made of the same metal materials should be used, otherwise the measurement result may be affected by electrode polarization.
- 6 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

**WARNING**

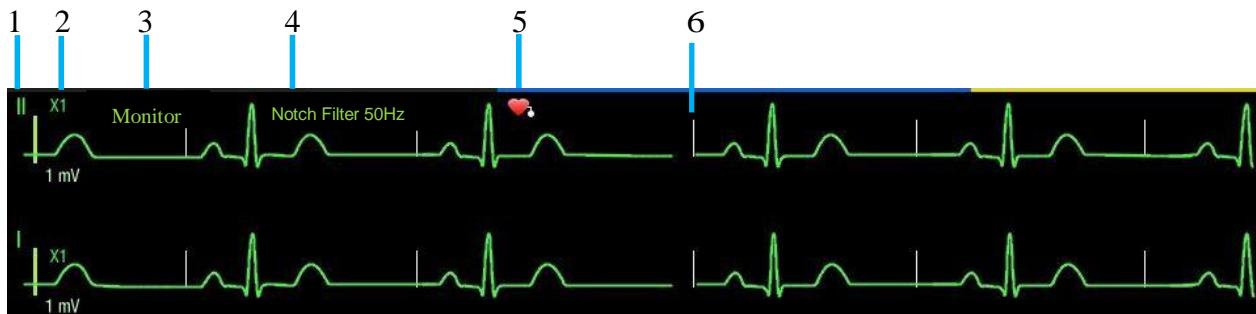
- 7 According to AAMI specifications, the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.
- 8 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION.
- 9 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should operate as *Preparation and Instaling Electrodes*.
- 10 Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.

**NOTE:**

- 1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.
- 2 IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

## 10.3 ECG Display

The figure below is for reference only.



1: Lead name of displayed waveform

4: Notch filter status

2: Waveform gain

5: Pace status

3: Filter mode

6: Pace pulse marker

## 10.4 ECG Monitoring Procedure

### 10.4.1 Preparing Skin

The skin is a poor conductor of electricity. Preparation of the patient's skin is important for good electrode contact.

- Select sites with intact skin without impairment of any kind.
- Shave hair from sites if necessary.
- Clean the selected sites thoroughly to remove skin scurf and grease.
- Dry the skin completely before applying electrodes.

### 10.4.2 Connecting ECG Cables

1. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
2. Connect the ECG electrode to the ECG cable.
3. Plug the ECG cable into the ECG connector on the monitor.

#### PRECAUTION

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by the manufacturer.

### 10.4.3 Selecting Electrode Type

To change the electrode type, please:

1. Select the ECG parameter area to access the ECG Setup menu;
2. Set Electrode Type to 3 Electrodes, 5 Electrodes, 6 Electrodes, 10 Electrodes or Auto based on the lead used.

If Electrode Type is set to Auto and if you remove the electrodes, the monitor will automatically recognize the new Electrode Type and issue the ECG lead off alarm. Click Update Lead Setup button to clear the ECG lead off alarm.

### 10.4.4 Installing Electrodes

Select the ECG standard on the monitor for the lead being used:

1. Select Menu > System > User Maintain and enter the password;
2. Select Parameter Maintain > ECG > ECG Standard. AHA and IEC are optional.

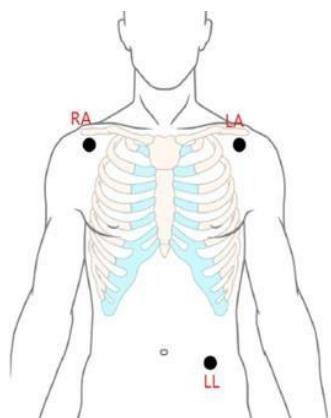
| AHA (American Standard) |               | IEC (Europe Standard) |               |
|-------------------------|---------------|-----------------------|---------------|
| Electrode Labels        | Color         | Electrode Labels      | Color         |
| RA                      | White         | R                     | Red           |
| LA                      | Black         | L                     | Yellow        |
| LL                      | Red           | F                     | Green         |
| RL                      | Green         | N                     | Black         |
| V                       | Brown         | C                     | White         |
| V1                      | Brown/ Red    | C1                    | White/ Red    |
| V2                      | Brown/ Yellow | C2                    | White/ Yellow |
| V3                      | Brown/ Green  | C3                    | White/ Green  |
| V4                      | Brown/ Blue   | C4                    | White/ Brown  |
| V5                      | Brown/ Orange | C5                    | White/ Black  |
| V6                      | Brown/ Purple | C6                    | White/ Purple |

NOTE: When connecting the electrodes, Ensure that the conductive parts of ECG electrodes and associated connectors, including the neutral electrode, do not come into contact with any other conductive parts including earth.

### 3 Electrodes Placement

Take the American standard for example, see the following figure:

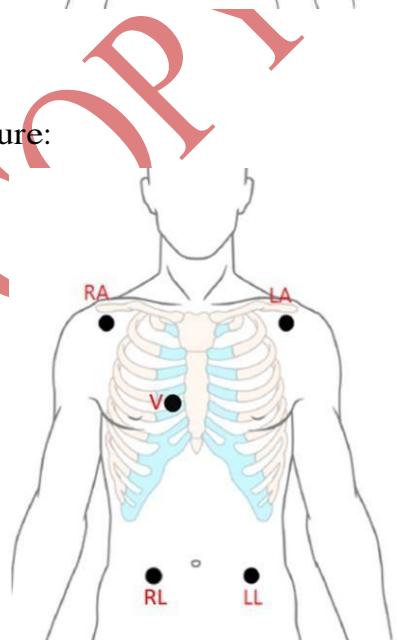
- RA placement - directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement - on the left hypogastrium.



### 5 Electrodes Placement

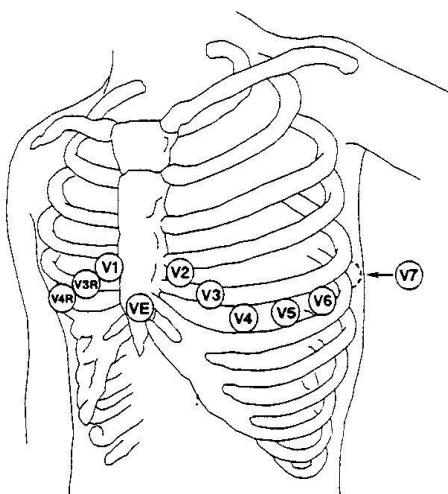
Take the American standard for example, see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right hypogastrium.
- LL placement: on the left hypogastrium.
- V placement: on the chest, the position depends on your required electrode selection.



- For 5 electrodes, attach the V electrode to one of the indicated positions as below:
- V1                  On the 4th intercostal space at the right sterna margin.
- V2                  On the 4th intercostal space at the left sterna margin.
- V3                  Midway between V2 and V4 electrodes.
- V4                  On the 5th intercostal space at the left clavicular line.
- V5                  On the left anterior axillary line, horizontal with V4 electrode.
- V6                  On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R            On the right side of the chest in positions corresponding to those on the left.
- VE                  Over the xiphoid position.

- V7 On the 5th intercostal space at the left posterior axillary line of back.
- V7R On the 5th intercostal space at the right posterior axillary line of back.

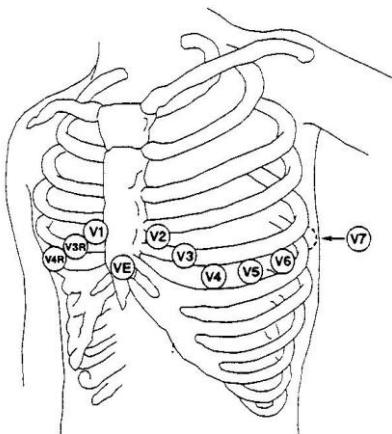


V-Electrode Placement for 5 Electrodes

## 6 Electrodes Placement

For the placement of 6 electrodes, please use the position of 5 electrodes in the schematic diagram to remove the two thoracic leads. The two thoracic leads Va and Vb can be placed at any two positions from V1 to V6, as shown in the following thoracic leads. To ensure that the label is correct, the selected Va and Vb placements must be set simultaneously in ECG Setup.

- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.



V-Electrode Placement for 6 Electrodes

## 10 Electrodes Placement

In 12-Lead ECG monitoring, the 10 electrodes are placed on the patient's four limbs and chest. The limb electrodes should be placed on the soft skin according to the physician's preference. The picture below shows the conventional 10 electrodes placement.

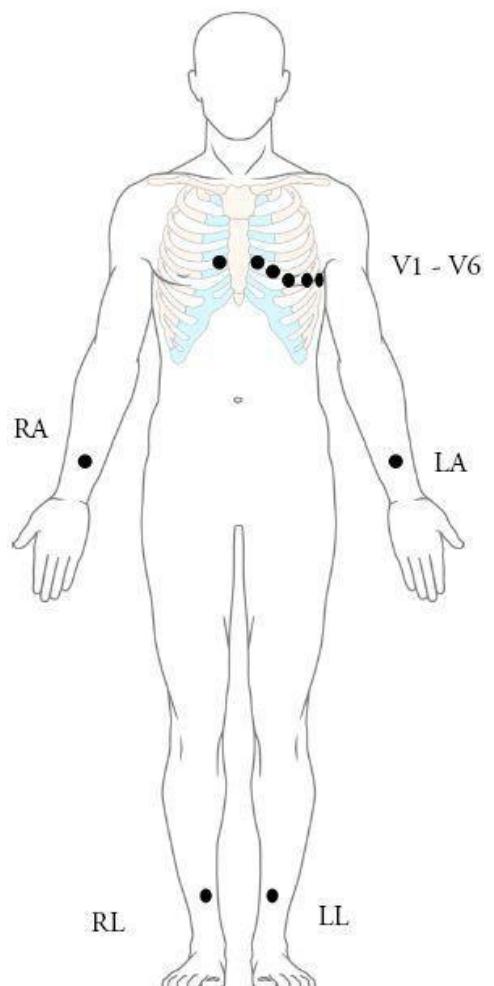
Take the American standard for example; the 10 electrodes should be placed as follows:

Limb electrodes:

- RA and LA: Place arm electrodes on the inside of each arm, between the wrist and the elbow.
- RL and LL: Place leg electrodes inside of each calf, between the knee and the ankle.

Chest electrodes:

- V1: On the 4th intercostal space at the right sterna margin.
- V2: On the 4th intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5th intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.



## Recommended ECG Electrode Placement for Surgical Patients

### WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position equal distance from the ES electrotome and the ES grounding plate to avoid cautery. ES equipment wires and ECG cables must be free from tangles.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other ES equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES equipment. To minimize interference, the electrodes can be placed on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms as the ECG waveform will be too small.

### WARNING

ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

## 10.5 ECG Setup

Select the ECG parameter area or waveform area to enter the ECG Setup menu.

### 10.5.1 Setting Analysis Mode

Select Analysis Mode in ECG Setup menu, and choose an appropriate setting from the pop-up list:

- Single-Lead: The monitor uses a lead (ECG1) as the analysis lead.
  - Multiple-Leads: The monitor uses four leads (ECG1~ECG4) as the analysis lead.
- Multiple-leads analysis improves the detection sensitivity and reduces the false alarm, but when most leads are disturbed and have low amplitude, it is recommended to

select the most suitable lead for single-lead analysis.

NOTE:

1. When Electrode Type is set to 3 Electrodes, the analysis mode function is not available and the monitor always adopts the single-lead analysis mode.
2. It is difficult for the monitor to distinguish between abnormal conduction beats and ventricular beats, and abnormal conduction beats may be misclassified as ventricular beats. It is recommended to select a narrower R-wave for ECG1 and to select a single-lead analysis mode.

### 10.5.2 Setting Alarm Source

To change the alarm source, please select either ECG Setup > Alarm Source or PR Setup > Alarm Source, then a pop-up list is displayed:

HR: the monitor considers the HR as HR/PR alarm source;

PR: the monitor considers the PR as HR/PR alarm source;

Auto: If the alarm source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and valid HR values are available. The monitor will automatically switch to PR as the alarm source if:

- valid HR values can no longer be measured and
- a PR source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. If valid HR values become available again, the monitor automatically uses HR as alarm source.

### 10.5.3 Setting QRS Tone Source

To change the QRS tone source, select either ECG Setup > QRS Tone Source or PR Setup > QRS Tone Source. Select from the following options:

HR: HR is HR/PR QRS tone source;

PR: PR is HR/PR QRS tone source;

Auto: If the QRS Tone Source is set to Auto, the monitor will use HR as the QRS tone source whenever the ECG measurement is switched on, and valid HR values are available. The monitor will automatically switch to PR as the QRS tone source if:

- valid HR values can no longer be measured and
- a PR source is switched on and available.

If an ECG lead becomes available again, the monitor automatically uses HR as QRS tone source and the monitor gives a “Di” tone when one heartbeat is detected. While a pulse is detected, the monitor gives a “Da” tone.

#### 10.5.4 Setting ECG SQI

The ECG SQI indicates the signal quality of the ECG analysis leads. In the ECG Setup menu, enable ECG SQI. The default setting is off. When it is enabled, the ECG SQI icon will be displayed in the ECG parameter area to indicate 10 different levels of HR signal intensity.

#### 10.5.5 Smart Lead OFF

When Electrode Type is 5 Electrodes, 6 Electrodes or 10 Electrodes and Smart Lead Off is set to on, if the selected ECG waveform cannot be measured because of lead-off or other reasons, it will automatically switch to another available lead channel via which a waveform can be measured. When the detached ECG lead is re-connected, the monitor automatically switches back to the original lead.

NOTE: When Electrode Type is set to Auto, the smart lead off function will be automatically turned on and cannot be turned off.

#### 10.5.6 Setting Pace

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status in the ECG Setup menu, select Pace to toggle between ON, OFF or Unknown. When Pace is set to ON: Pace pulse marker is displayed as ' on the ECG waveform.

When monitoring a patient with a pacemaker, set Pace to ON. If monitoring a patient without a pacemaker, set Pace to OFF.

When Pace is set to Unknown, the monitor will continuously monitor the pace status and prompt the information when the pace signal is detected. Meanwhile,  will be displayed in the ECG waveform area, in order to prompt the user to turn on the pace analysis.

**WARNING**

- 1 Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Be sure to check the paced symbol on the display screen has correctly detected the pacing pulse. Keep pacemaker patients under close observation.
- 2 For patients with pacemakers, the pace must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected. When changing settings and admitting patients, please make sure the pace mode is always correct.
- 3 External pacing electrodes: When a pacemaker with external pacing electrodes is being used on a patient, arrhythmia monitoring is severely compromised due to the high energy level in the pacer pulse. This may result in the arrhythmia algorithm's failure to detect Pacer not Captured or asystole.

To enable the pace pulse rejection function, switch on Pace Pulse Rejection in ECG Setup menu. When it is enabled, pacemaker pulses are rejected and will not be displayed on the ECG waveform.

**NOTE:**

- 1 The pace pulse rejection can be adjusted only when Pace is set to ON.
- 2 The display of pace pulse marker<sup>1</sup> is not affected by the pace pulse rejection setting.
- 3 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.
- 4 Pacer not Capture and Pacer not Pacing alarms are available only when Pace is set to On.

## 10.5.7 ECG Waveform Setup

### 10.5.7.1 Selecting the Lead Name

You can set the lead name of each ECG waveform on the ECG setting screen. If more than three waveforms are displayed, select More Leads to set the lead names of other waveforms (ECG3, ECG4).

Choose a lead that has the following characteristics:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

NOTE:

Make sure you have selected the best lead with the best waveform amplitude and highest signal-to-noise ratio. Choosing the best lead is important for heart beat test, heart beat classification and ventricular fibrillation detection.

#### 10.5.7.2 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select Waveform Gain in ECG Setup menu, and then select an appropriate factor from the pop-up list to adjust the ECG waveform. If it is set to Auto, the monitor automatically adjusts the size of all the ECG waveforms.

NOTE: The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area, the exceeded part is clipped.

#### 10.5.7.3 Setting the Speed of the ECG Wave

To change the speed, select Speed in ECG Setup menu, and then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

#### 10.5.7.4 Setting Va and Vb Labels

If 6 Electrodes is selected in the ECG Setup menu, Va and Vb can be respectively set to either Lead V1 ~ V6, but cannot be set to the same lead. Va is Lead V1 by default and Vb is Lead V2 by default.

#### 10.5.7.5 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed.

To change the filter setting, in the ECG Setup menu, select Filter and then select the appropriate setting.

– Monitor: Select Menu > System > User Maintain and enter the password > Parameter Maintain > ECG to set Monitor Type: Normal or Hi-Fi.

- Normal: Use this mode under normal measurement conditions.

- Monitor (Hi-Fi): In the normal measurement state, the signal is expected to not be distorted, the waveform has a high fidelity, and the signal delay is 1~2 s; It can also be used for ST segment analysis.
- Diagnosis: Use this mode when undistorted quality is required and its own characteristics can be maintained. The waveform filtered by the bandwidth of 0.05 Hz~150 Hz is displayed so that the actual changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.
- Surgery: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting Surgery may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.
- Enhanced: It should be used if the signal is distorted by strong interference from high frequency or low frequency. If there is still obviously interference in the signals when select surgery filter mode, it is recommended to choose the enhanced mode. In this mode, QRS wave rhythm information is emphasized, its shape information cannot be considered as diagnostic criteria. Under normal measurement conditions, the selection of this mode may inhibit QRS wave group and interfere ECG analysis.
- ST: To meet the filtering requirements of ST analysis, it is used when ST analysis is turned on or when ST analysis results are concerned.
- Customized: User can set High-pass Filter and Low-pass Filter as needed. Cutoff frequency of High-pass can be selected as: 0.01 Hz, 0.05 Hz, 0.15 Hz, 0.25 Hz, 0.32 Hz, 0.5 Hz and 0.67 Hz. Cutoff frequency of Low-pass Filter can be selected as: 25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz, and 150 Hz. After High-pass filter and Low-pass Filter are set, the bandwidth range of high – pass bandwidth to low - pass bandwidth can be formed.

#### 10.5.7.6 Setting Notch Filter

The notch filter can screen out 50 Hz/60 Hz power frequency interference. Select Notch Filter in ECG Setup menu, and then select an appropriate setting from the pop-up list. OFF, 50 Hz and 60 Hz are optional. The default setting is 50 Hz.

## 10.6 Arrhythmia Monitoring

### 10.6.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, detect the changes of heart rate and ventricular rhythm, save arrhythmia events, and generate alarm information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

**NOTE:** The measured PVCs and Pause/min will be displayed in main interface.

| Arrhy Alarms             | Occurring Condition  |
|--------------------------|--|
| <b>Asystole</b>          | No QRS is detected for 4 consecutive seconds.  |
| <b>V-Fib/V-Tach</b>      | 4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR $\geq 100$ bpm.  |
| <b>Couplet</b>           | 2 consecutive PVCs.  |
| <b>Run PVCs</b>          | $3 \leq$ the number of consecutive PVCs $< 5$ .  |
| <b>PVC Bigeminy</b>      | A dominant rhythm of N, V, N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.  |
| <b>PVC Trigeminy</b>     | A dominant rhythm of N, N, V, N, N, V, N, N, V.  |
| <b>R on T</b>            | A type of single PVC under the condition that HR $< 100$ , R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave). |
| <b>PVC</b>               | Single PVC detected in normal heartbeats, and the number of consecutive single PVC $\geq 4$ within 30 s.   |
| <b>Tachy</b>             | Adult: RR interval for 5 consecutive QRS complex $\leq 0.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq 0.375$ s.  |
| <b>Brady</b>             | Adult: RR interval for 5 consecutive QRS complex $\geq 1.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq 1$ s.  |
| <b>Missed Beat</b>       | If HR $< 120$ bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq 120$ bpm, no beats are detected for one second.  |
| <b>Irr Rhythm</b>        | Consistently irregular heart rhythm.   |
| <b>Pacer not Capture</b> | No QRS complex detected in 300 ms after a pace pulse.  |
| <b>Pacer not Pacing</b>  | No pace pulse detected in 1.75 times RR interval after a QRS complex.  |
| <b>Vent Brady</b>        | 5 consecutive ventricular beats, and ventricular HR $< 20$ bpm.  |

| Arrhy Alarms  | Occurring Condition  |
|---|--|
| <b>Vent Rhythm</b>  | 5 consecutive ventricular beats, and $20 \text{ bpm} \leq \text{ventricular HR} < 40 \text{ bpm}$ .  |
| <b>PVCs High</b>  | The measurement value of PVCs is greater than high alarm limit that has been set.  |
| <b>Sustain VT</b>   | The duration of ventricular tachycardia rhythm $>$ the threshold value that has been set.  |
| <b>ExtremeTachy</b>   | $\text{HR} > \text{Extreme Tachycardia threshold value}$ that has been set.  |
| <b>ExtremeBrady</b>   | $\text{HR} < \text{Extreme Bradycardia threshold value}$ that has been set.  |
| <b>V-Tach</b>   | 5 consecutive ventricular beats and ventricular HR $\geq 100 \text{ bpm}$ .  |
| <b>Wide QRS Tachy</b>   | Meet tachycardia conditions, and QRS wave width $\geq 160 \text{ ms}$ .  |
| <b>Non-Sustain VT</b>   | $3 \leq \text{The number of consecutive ventricular beats} < 5$ , and ventricular HR $\geq 100 \text{ bpm}$ .  |
| <b>Afib</b>   | Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist. |
| <b>Acc. Vent</b>  | 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$ .   |
| <b>Pause</b>  | No QRS is detected within the heartbeat pause threshold value that has been set.   |
| <b>Pause/min High</b>   | The measurement value of Pause/min is greater than high alarm limit that has been set.   |
| <b>VEB</b>  | The delayed ventricular beats detected in normal heartbeats occur more than or equal to 2 times within 30 s.   |
| <b>Multiform PVCs</b>   | Different forms of ventricular premature beats are detected in 15 beats.   |
| <b>IPVC</b>   | The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.   |
| <b>PAC Bigeminy</b>   | The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).                       |
| <b>PAC Trigeminy</b>  | The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.   |
| <b>Low Voltage(Limb)</b>  | The signal amplitudes of I, II and III leads shall not exceed alarm threshold value that has been set.<br>PS: this alarm is available for 5 or 12 leads only, not available for 3 leads.   |
| NOTE: Arrhythmia monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended setting for arrhythmia monitoring in neonatal and pediatric modes is OFF. |  |

Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude > 0.5 mV)
- R wave should be above or below the baseline (but not biphasic)
- T wave should be smaller than 1/3 of the R wave height
- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker signal should also:

- not wider than normal QRS
- The QRS complexes should be at least twice the height of the pacing pulse

According to Standard IEC 60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) will not influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

#### Aberrantly-Conducted Beats:

As P waves are not analyzed, it is difficult for the monitor to distinguish between an aberrantly-conducted beat and a ventricular beat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Always select a lead where the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize incorrect calls. The ventricular should look different than “normal heartbeat”. Doctors should keep patients with aberrantly-conducted beats under close observation.

#### Intermittent bundle branch block:

The bundle branch block or other bundle obstruction phenomenon is a challenge for the arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the learned normal QRS, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. The lead that blocks the R-wave heartbeat as narrow as possible must be selected to minimize the wrong classification. Ventricular heartbeat should look different than “normal heartbeat”. Doctors should keep patients with bundle branch block under close observation.

#### NOTE:

- 1 Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia.

- Always keep these patients under close surveillance.
- 2 Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, there may be some false arrhythmias detected; some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
  - 3 Atrial fibrillation analysis is only applicable to adult patients.

### 10.6.2 Arrhythmia Analysis Menu

#### 10.6.2.1 Enabling Arrhythmia Analysis

To switch on Arrhythmia analysis, follow these steps:

1. Select the ECG parameter area or waveform area to enter the ECG dialog.
2. Select the Arrhythmia tab > Setup tab.
3. Enable ARR Analysis.

#### 10.6.2.2 Arrhythmia Alarm Setup

Asystole and Sustain VT alarms are key arrhythmia alarms and they are preset to be on and cannot be turned off.

The user can switch on/off arrhythmia alarms only when Alarm Switch Setup is enabled. To enable the authority,

1. Select Menu > System > User Maintain, and enter the required password.
2. Select Alarm Setup and set Alarm Switch Setup to Enable. If any of key arrhythmia alarms is switched off, the monitor will give prompts.

Select Arrhythmia tab > Alarm tab to change the following arrhythmia alarm settings:

- Separately switch on or off each arrhythmia alarm and set the alarm level/record.
- Select All Alarms On/All Alarms Off to switch on or off all arrhythmia alarms except Asystole and Sustain VT alarms.
- Set the threshold of certain arrhythmia alarms. When an arrhythmia exceeds its threshold, an alarm will be triggered.

Confirm the changes to make the settings effective.

#### **WARNING**

When the arrhythmia alarm is set to OFF, the monitor will not give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient life, this function should be used cautiously.

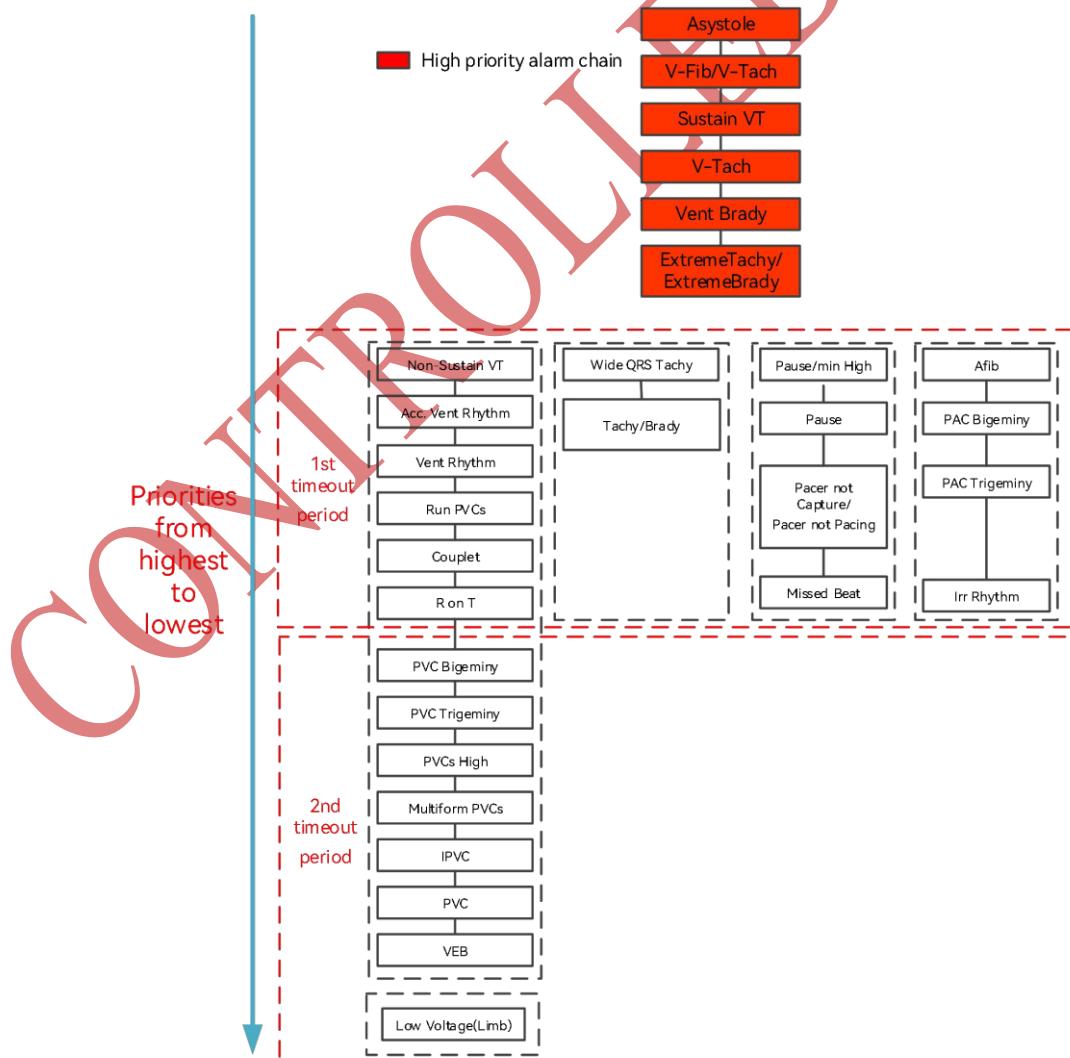
NOTE: Pacer not Capture and Pacer not Pacing alarms are available only when Pace is set to ON.

### 10.6.2.3 Adjustable Range of Arrhythmia Alarm Threshold

| Arrhythmia Alarm  | Range  |
|-------------------|--|
| PVCs High         | 1/min to 99/min  |
| Pause/min High    | 1/min to 20/min  |
| Pause             | 2 s, 2.5 s, 3 s  |
| Sustain VT        | 15 s to 45 s   |
| ExtremeTachy      | Adult: 120 bpm to 300 bpm;<br>Pediatric/neonatal: 120 bpm to 350 bpm |
| ExtremeBrady      | 15 bpm to 60 bpm   |
| PAC Bigeminy      | 3 to 50 groups of NA or NNA  |
| PAC Trigeminy     |  |
| Low Voltage(Limb) | 0.3 mV to 0.8 mV   |

### 10.6.2.4 Arrhythmia Alarm Timeout

If multiple alarm conditions occurs, announcing all of the detected alarm conditions would be confusing, and might hide a more serious condition. Therefore, the arrhythmia system defines alarm priorities through an alarm chaining system.



Normally, an arrhythmia alarm is announced when an alarm condition is detected. However, there are certain situations that can inhibit the audible and visible indications of the alarm even though the alarm condition was detected. Select Arrhythmia tab > Setup tab to set the arrhythmia timeout period: 1st Timeout Period and 2nd Timeout Period. The arrhythmia algorithm can disable alarm light and alarm tone for designated period of time when certain arrhythmia alarms are detected.

#### Alarm Chaining Logic:

| Previous Alarm               | Current Alarm                                | Alarm Indication   |
|------------------------------|--|--|
| High priority alarm chain    | Any alarm                                    | Alarm light and alarm tone   |
| Alarms in 1st timeout period | High priority alarm chain                    | Alarm light and alarm tone   |
|                              | Alarms in 1st timeout period (high priority) |  |
|                              | Same alarm triggered again                   | Disable the alarm light and alarm tone during the timeout period.        |
|                              | Alarms in 1st timeout period (low priority)  | Restore the alarm light and alarm tone when the timeout period ends.     |
|                              | Alarms in 2nd timeout period                 |  |
| Alarms in 2nd timeout period | High priority alarm chain                    | Alarm light and alarm tone   |
|                              | Alarms in 1st timeout period                 |  |
|                              | Alarms in 2nd timeout period (high priority) |  |
|                              | Same alarm triggered again                   | Disable the alarm light and alarm tone during the timeout period.        |
|                              | Alarms in 2nd timeout period (low priority)  | Restore the alarm light and alarm tone when the 2nd timeout period ends. |

NOTE: Alarms in the high priority chain do not have a timeout period. The alarm light and alarm tone are generated as soon as the alarm condition is detected.

#### 10.6.2.5 Arrhythmia Relearning

Pick this item Start ARR Relearning to start a learning procedure, and ARR Relearning is displayed on the screen.

The Arrhythmia relearning will start automatically in the following status:

- Switching the Arrhythmia Analysis from OFF to ON;

- Changing patient type or electrode type;
- Connecting or switching ECG1~ECG4;
- Changing pacemaker status;
- Exiting Standby mode;
- Admitting a patient;
- Switching calibration mode into normal measurement mode;
- Switching the ECG parameter on;
- Switching the analysis mode.

NOTE:

- 1 During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.
- 2 Take care to initiate Arrhythmia relearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If Arrhythmia relearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.
- 3 If Arrhythmia relearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.

Due to this reason, you should:

- 1) Take care that Arrhythmia relearning may start automatically;
- 2) Response to lead off information;
- 3) Always check the correctness of arrhythmia alarm.

## 10.7 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrial beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and ST templates on the monitor.

ST segment monitoring function is disabled by default. You enable ST Analysis when necessary.

To switch on ST analysis, follow these steps:

1. Select the ECG parameter area or waveform area to enter the ECG dialog.
2. Select the ST tab > Setup tab. Enable ST Analysis.

In ST analysis, the obtained ST value and ST template are all unaffected by the selected filter mode. ST algorithm itself uses a dedicated linear filter to ensure the

signal is not distorted, and to better ensure the consistent and accurate measurement value and ST template can be obtained in different filter modes. If the doctor wants to observe the waveform to evaluate ST segment result, it is recommended to use the ST template for observation, as it is not affected by the filter mode. If the real-time waveform displayed on the interface is used to evaluate ST segment result, it is recommended to select Diagnosis/ST mode.

**NOTE**

:

1 ST-segment analysis is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended and default setting for ST analysis in neonatal and pediatric modes is OFF.

2 Reliable ST monitoring may be influenced in following situations:

- You are unable to get a lead with low noise.
- If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.
- The patient is continually performing ventricular paced.
- The dominant template cannot be obtained for a long time.
- The patient has left bundle branch block.

When any of above situations happens, ST monitoring should be switched off.

- 3 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.
- 4 If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts may be depressed or raised. Always ensure that the ST measurement point is suitable for your patient.
- 5 ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- 6 ST is calculated with a fixed delay from the R position. Changes in heart rate or the width of QRS may affect ST.
- 7 If the algorithm triggers self-learning (either manually or automatically), the calculation of ST segment will be reinitialized.

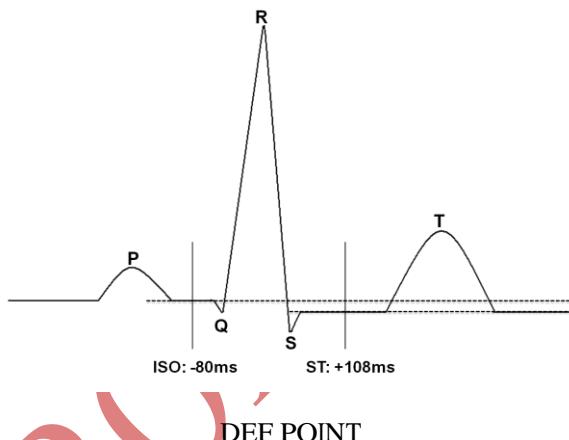
### 10.7.1 ST Display

Your monitor screen may be configured to look slightly different from the illustrations. A positive ST value indicates ST segment elevation and a negative value indicates depression.

|    |     |      |     |       |      |      |
|----|-----|------|-----|-------|------|------|
| ST | I   | 0.08 | aVR | -0.09 | V    | 0.04 |
|    | II  | 0.10 |     | aVL   | 0.03 |      |
|    | III | 0.02 |     | aVF   | 0.06 |      |

### 10.7.2 About ST Measurement Points

The ST value for each QRS complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment.



The ST and ISO measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly. Always ensure that ST measurement points are appropriate for your patient.

### 10.7.3 Adjusting ST and ISO Measurement Points

To adjust the ST measurement points, follow these steps:

1. Select Analysis Point Setup in ST Setup menu.
2. Input the appropriate value to move the cursor line left or right.

### 10.7.4 ST VIEW

The ST View displays a complete QRS segment for each ST lead. The color of current ST segment and ST value are consistent with the color of HR. The color of baseline and ST value are yellow. To enter ST view, select ST VIEW in ST Setup menu.

In the ST View interface, the user can save ST baseline by clicking Save Baseline when ST values gets stable. If no ST baseline is saved, the monitor automatically saves the baseline when the first valid and complete ST waveform appears.

In the ST View interface, the user can also perform the following operations:

- Display or hide ST baseline by selecting Show Baseline or Hide Baseline.
- Display or hide ST points by selecting Show Points or Hide Points.

### 10.7.5 ST Histogram

The monitor can derive a ST Histogram from the ST analysis to help you detect changes in ST values. To enter ST Histogram, select ST Histogram in ST Setup menu. The horizontal axis shows the lead name while the vertical axis shows the ST value. The bar graph displays the ST value of corresponding ST lead. The color of the bar graph indicates ST status: cyan indicates that corresponding ST value is within normal range; yellow and orange indicate that the ST value is out of normal range. The ST histogram refreshes with ST View synchronously.

## 10.8 QT Analysis

The QT interval is the time from the beginning of Q wave to the end of T wave. It measured the total duration of the depolarization (QRS duration) and repolarization (ST-T) phases of ventricular action potential. QT analysis can help detect Long QT Syndrome.

### 10.8.1 Measurement Limitations

The following clinical status of the patient may affect the QT analysis, and the inaccurate measurement may but is not limited to the following reasons:

- The T-wave is very flat;
- Atrial flutter and atrial fibrillation make T wave is difficult to define;
- The end of the T-wave is difficult to define because of the presence of U-waves;
- A high heart rate causes the P-wave to encroach on the end of the previous T-wave;
- Noise or the QRS wave variation is too big.

In these cases, the user should choose a lead with good T wave amplitude and no visible oscillations, and without a dominant U wave or P wave.

In some conditions, such as left or right bundle branch block or cardiac hypertrophy causes broaden QRS complex. If long QTc is observed, verify it to ensure that it is not caused by QRS broadening.

Since normal beats followed by ventricular beats are not included in the analysis, QT measurement could not be carried out when there was bigeminy rhythm.

When the heart rate changes, it may take several minutes for the QT interval to stabilize. In order to obtain reliable QTc calculations, it is important to avoid areas where the heart rate changes.

**NOTE: QT/QTc measurements should always be validated by a qualified clinician.**

### 10.8.2 Enabling QT Analysis

To switch on QT analysis, follow these steps:

1. Select the ECG numeric area or waveform area to enter the ECG dialog.
2. Select the QT tab > Setup tab.
3. Enable QT Analysis.

### 10.8.3 QT Display

The following figure is QT display for your reference only. The graphics on your monitor may be slightly different.



### 10.8.4 Selecting QT Analysis Lead

To adjust the QT analysis lead, select QT Leads in QT Setup menu.

There are two modes for selection:

**ALL:** Use all available leads (except the pressurized limb lead) to produce an overall QT measurement.

**Single lead:** Select a single lead from all available leads to perform QT measurement (except the pressurized limb lead).

### 10.8.5 Selecting QTc Formula

The monitor uses Bazett formula to correct QT values by default. To adjust the QTc formula, select **QTc Formula** in QT Setup menu. There are four alternative formulas: **Bazett, Fridericia, Framingham and Hodges.**

*Hodges:*  $QTc = QT + 1.75 \times (HR - 60)$

$$\text{Bazett: } QTc = QT \times \left( \frac{HR}{60} \right)^{1/2}$$

$$\text{Fridericia: } QTc = QT \times \left( \frac{HR}{60} \right)^{1/3}$$

$$\text{Framingham} = QTC = QT + 154 \times \left( 1 - \frac{60}{HR} \right)$$

### 10.8.6 QT VIEW

QT View shows the current and baseline QT parameter values and waveforms.

To enter QT view, select **QT VIEW** in QT Setup menu.

Users can select different leads for QT view. It varies depending on the QT Leads.

To quantitatively express the QTc values change, the user can set a QT baseline. The baseline is used for calculating  $\Delta QTc$  value. If no baseline has been set for this patient within the first five minutes after getting valid QT values, the monitor will automatically set a baseline.

To save the current values as baseline, select **Save Baseline**, and the monitor displays **Baseline Saved at: (Time)**. If a new baseline is set, the previous baseline is discarded. Because  $\Delta QTc$  alarm is based on the difference of the baseline with the current values, inappropriate baseline settings may lead that no  $\Delta QTc$  alarm is generated. Select **Display Baseline** or **Hide Baseline** to show or hide the QT baseline waveforms.

**NOTE: QTc values are calculated based on the QT-HR, not the ECG HR.**

### 10.9 ECG Calibration

Select Menu > System > User Maintain and input user maintenance password > Parameter Maintain > ECG > Start Calibration to calibrate ECG waveform. When you select this item again, the ECG waveform calibration ends.

**NOTE:** The patients cannot be monitored during the ECG calibration.

# Chapter 11 Monitoring RESP

## 11.1 Overview

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

Respiration may also be measured by CO<sub>2</sub> module. See Section Monitoring CO<sub>2</sub> for respiration information.

## 11.2 RESP Safety Information

### WARNING

- 1 If you do not set the Hold High and Hold Low for the respiration correctly in manual detection mode, the monitor may prompt false alarm for apnea, or make inaccurate measurement, or be hard to detect apnea. If you set the Hold High and Hold Low too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.
- 2 Respiration measurements cannot detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it cannot be used for diagnostic purposes.
- 3 If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.
- 4 To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories required to be used for electrosurgical operation is too large.

**WARNING**

- 5 Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as etCO<sub>2</sub> and SpO<sub>2</sub>.
- 6 For the diagnosis of apnea, especially in premature infants and infants, the safety and effectiveness of respiration measurements have not been validated.
- 7 Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate." Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.
- 8 In manual detection mode, after changing the gain of the respiration wave, be sure to check the setting of hold high and hold low.
- 9 Respiration measurement cannot be performed when ESU is used.
- 10 RESP No Breath Detected alarm should not be used or relied upon while the patient is unattended.

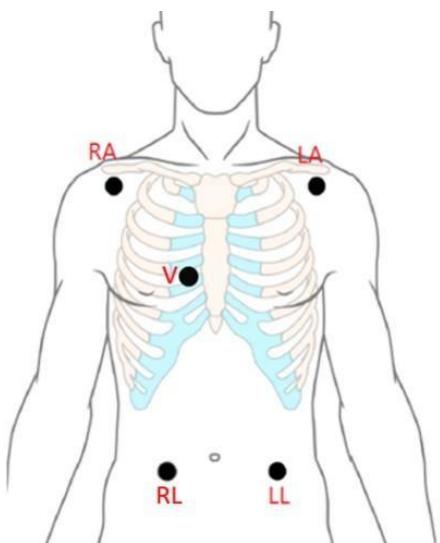
**NOTE:**

- 1 The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.
- 2 When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.

### 11.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation for electrode placement is important for RESP measurement. See the chapter on ECG for more information.

The RESP signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).



Electrodes Placement for 5 Electrodes

Cardiac activity that affects the RESP waveform is called cardiac overlay. This occurs when the RESP electrodes detect impedance changes caused by the rhythmic blood flow. Correct electrode placement can reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

Some patients, especially neonates, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

#### 11.4 Setting RR Source

Set RR Source to CO<sub>2</sub>, ECG or Auto in RESP Setup menu. The RR source is displayed in the RESP parameter area.

When it is set to Auto, the monitor automatically selects the RR source with the following priority: CO<sub>2</sub> > ECG.

When the manually selected RR source is not available, the monitor automatically switches the RR Source to Auto. When the manually selected RR source is available, the monitor automatically switches back to the original RR source.

## 11.5 Selecting RESP Lead

To set the respiration lead to II or I to obtain the best respiratory waveform, select RESP Lead in RESP Setup menu.

## 11.6 Changing Hold Type

Change the calculation mode in the RESP Setup menu, set Hold Type to Manual or Auto. When it is set to the Auto mode, Hold High and Hold Low are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to the Manual mode, you can adjust the detection threshold of the respiration wave.

## 11.7 Setting the Respiration Wave

In the RESP Setup menu:

- Select Scale and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.
- Select Speed and select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform will be.

## 11.8 Changing the No Breath Detected Alarm Time

The No Breath Detected alarm is a high priority red alarm used to detect apneas. The No Breath Detected alarm delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the No Breath Detected alarm. Users should set it cautiously.

1. In the RESP Setup menu, select No Breath Detected.
2. Select the appropriate setting from the pop-up list.

## Chapter 12 Monitoring SpO<sub>2</sub>

### 12.1 Overview

SpO<sub>2</sub> is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO<sub>2</sub> parameter can also provide pulse rate (PR) and a plethysmogram wave (Pleth). This device is calibrated to display functional oxygen saturation of arterial hemoglobin.

### 12.2 SpO<sub>2</sub> Safety Information

#### **WARNING**

- 1 Do not use the SpO<sub>2</sub> sensors if the packaging or the sensor is damaged and return them to the vendor. If the SpO<sub>2</sub> sensor cannot work properly, please reconnect the sensor or change a new one.
- 2 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect the if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.
- 3 Use only sensors and extension cables permitted by the manufacturer with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.
- 4 High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.

**WARNING**

- 
- 5 Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.
- 

**NOTE:**

- 1 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line, or inflated NIBP cuff. When measuring SpO<sub>2</sub> on the limb with inflated NIBP cuff, please turn on the NIBP Simul function.
- 2 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.
- 3 The SpO<sub>2</sub> pleth waveform is not normalized and is not directly proportional to the pulse volume.
- 4 A Functional tester or simulator cannot be used to assess the SpO<sub>2</sub> accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.
- 5 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35 °C, the temperature of all the listed sensors on the skin will not exceed 41°C during working.
- 6 The cumulative use time for the SpO<sub>2</sub> sensor in a single patient should be less than 30 days.

### 12.3 SpO<sub>2</sub> Measurement Limitations

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application
- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight
- failure to cover the sensor with opaque material in high levels of ambient light

conditions

- dysfunctional hemoglobins
- low peripheral perfusion
- excessive or violent patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly
- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor
- low peripheral perfusion

NOTE:

- 1 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.
- 2 Adjacent SpO<sub>2</sub> sensors may interfere with each other (eg, multiple SpO<sub>2</sub> measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.
- 3 Move the sensor to a less active site.
- 4 When serious arrhythmia is present, the SpO<sub>2</sub> pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO<sub>2</sub>) value.

## 12.4 SPO<sub>2</sub> Display



- |                                  |                          |
|----------------------------------|--------------------------|
| 1 Plethysmogram wave (Pleth)     | 2 SpO <sub>2</sub> label |
| 3 SpO <sub>2</sub> value         | 4 Perfusion Index        |
| 5 Perfusion Indicator (Blip Bar) |                          |

#### 12.4.1 Perfusion Indicator (Blip Bar)

The Blip Bar indicates pulse beat and the relative (non-normalized) pulse amplitude. As the detected pulse becomes stronger, more bars light with each pulse.

#### 12.4.2 PI (Perfusion Index)

PI (Perfusion Index) gives a percentage for the pulsatile signal to the non-pulsatile signal at the monitoring site. PI reflects the perfusion level at the monitoring site, which can also indicate arterial pulse signal strength. PI is indicated by a percentage ranging from 0.05% to 20%. PI below 0.1% indicates the low perfusion at the monitoring site. Reposition the sensor or find a better site.

### 12.5 Measuring SpO<sub>2</sub>

1. Select the correct patient category setting (Adult/Pediatric and Neonate), as this is used to optimize the calculation of the SpO<sub>2</sub> and pulse numerics.
2. During measurement, ensure that the application site:
  - has a pulsatile flow, ideally with a good circulation perfusion.
  - has not changed in its thickness, causing an improper fit of the sensor.

#### Measurement Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient.

#### Before Applying the Sensor:

Be sure to understand all warnings listed in the previous section before applying any sensor to a patient. Also, check the sensor as follows:

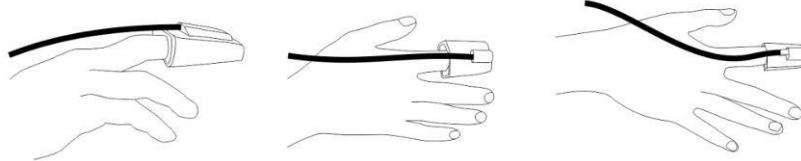
- ♦ Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- ♦ Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of it using proper disposal procedures.

#### Applying Finger/Soft-tip Sensors:

- ♦ Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The ring finger of the non-dominant hand is preferred.

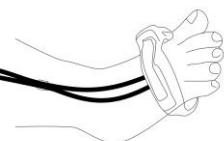
Alternatively, the other fingers on the non-dominant hand may be used.

- ♦ The big toe or long toe (next to the big toe) may be used on restrained patients or patients whose hands are unavailable.
- ♦ Place the finger into the sensor according to the direction of the symbol on the sensor. Adjust the finger to ensure that the pad of the finger completely covers the sensor detection window.
- ♦ Orient the sensor so that the cable will be running towards the top of the patient's hand.
- ♦ Connect the sensor with the monitor (or with the extension cable if needed).



#### Applying Neonatal Finger (or Toe) Wrap Sensors:

- ♦ When you perform the measurement, position the sensor over the hand or foot with optical components opposite each other.
- ♦ Hold the sensor, and insert stretched strap into slot, hold it there while threading end through latch. If strap is too long, thread it through second latch.
- ♦ Connect the sensor with the monitor (or with the extension cable if needed).



#### Applying Adult/Pediatric Ear Clip Sensor:

- ♦ When you perform the measurement, clip the plastic fixing part on top of the ear; reinforce it to prevent falling off or getting loose.
- ♦ Clip the probe onto fleshy part of the lobe with optical components opposite to each other.
- ♦ Connect the sensor with the monitor (or with the extension cable if needed).



3. Plug the connector of the sensor extension cable into the SpO<sub>2</sub> socket.

**WARNING**

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours (or more often, if indicated by circulatory status and/or skin integrity). For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently. Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.

**NOTE:**

- 1 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- 2 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. See Directions for Use for the application of each sensor.
- 3 Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

## 12.6 Assessing the Validity of a SpO<sub>2</sub> Reading

You can check the quality of the pleth wave and the stability of the SpO<sub>2</sub> values to assess whether the sensor functions properly and whether the SpO<sub>2</sub> readings are valid. Always use these two indications simultaneously to assess the validity of a SpO<sub>2</sub> reading.

Generally, the quality of the SpO<sub>2</sub> pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor-quality manifests a decline of the signal validity. On the other hand, the stability of the SpO<sub>2</sub> values also reflects the signal quality. Different from varying SpO<sub>2</sub> readings caused by physiological factors, unstable SpO<sub>2</sub> readings are resulted from the sensor's receiving signals with

interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO<sub>2</sub> readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

The SpO<sub>2</sub> accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO<sub>2</sub> measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of healthy men and women from age 18 to 50, with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

NOTE:

- 1 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).
- 2 During monitoring, if the monitor's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.
- 3 Sensor movement, ambient light (especially strobe lights or flashing lights) or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached. Especially wrap sensor designs are sensitive to minimal sensor movement that might occur when the sensor is dangling.

## 12.7 SpO<sub>2</sub> Setup

Select the SpO<sub>2</sub> parameter area or waveform area to access the SpO<sub>2</sub> Setup menu.

### 12.7.1 Setting Sensor Light Intensity Display

In the SpO<sub>2</sub> Setup menu, select Sensor Light Intensity to toggle between ON and OFF. The default setting is OFF. When it is set to enabled, the sensor light intensity icon  will be displayed in the SpO<sub>2</sub> parameter area to indicate five different levels of intensity.

### 12.7.2 Setting NIBP Simul

While measuring SpO<sub>2</sub> and NIBP on the same limb simultaneously, the user can set NIBP Simul to enabled in the SpO<sub>2</sub> Setup menu to lock the SpO<sub>2</sub> alarm status until the NIBP measurement ends. If NIBP Simul is disabled, low perfusion caused by NIBP measurement may lead to inaccurate SpO<sub>2</sub> readings and therefore cause false physiological alarms.

### 12.7.3 Setting Pitch Tone

In the SpO<sub>2</sub> Setup menu, select Pitch Tone to toggle between ON and OFF. If tone modulation is on, the PR sound lowers when the SpO<sub>2</sub> level drops.

### 12.7.4 Setting Sensitivity

The different sensitivity indicates different refresh frequency. High indicates the refresh frequency of SpO<sub>2</sub> value is the most frequent. To change the sensitivity, please follow the steps:

1. Select the SpO<sub>2</sub> Setup menu;
2. Select Sensitivity on the interface and select the desired sensitivity from the pop-up list.

### 12.7.5 Setting Waveform Speed

To set the speed of Pleth waveforms, follow these steps:

1. Select the SpO<sub>2</sub> Setup menu;
2. Choose Speed and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

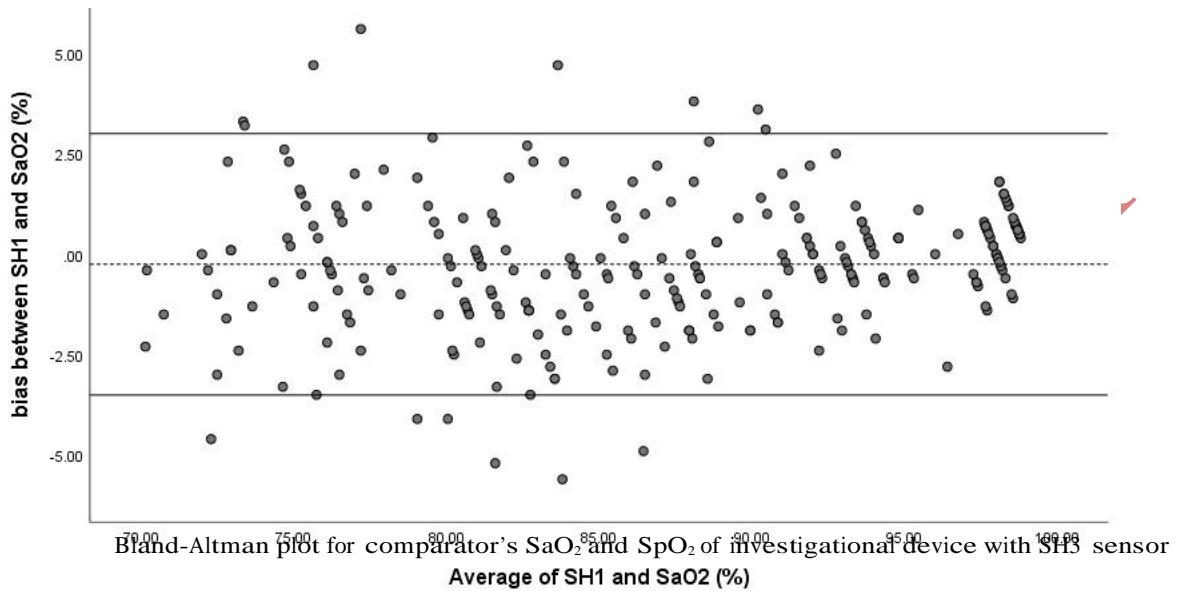
## 12.8 SpO<sub>2</sub> Relevant Data for Reference

1. The table below shows Arms values measured using SH series sensors and ear clip sensor with CX Series in a clinical study

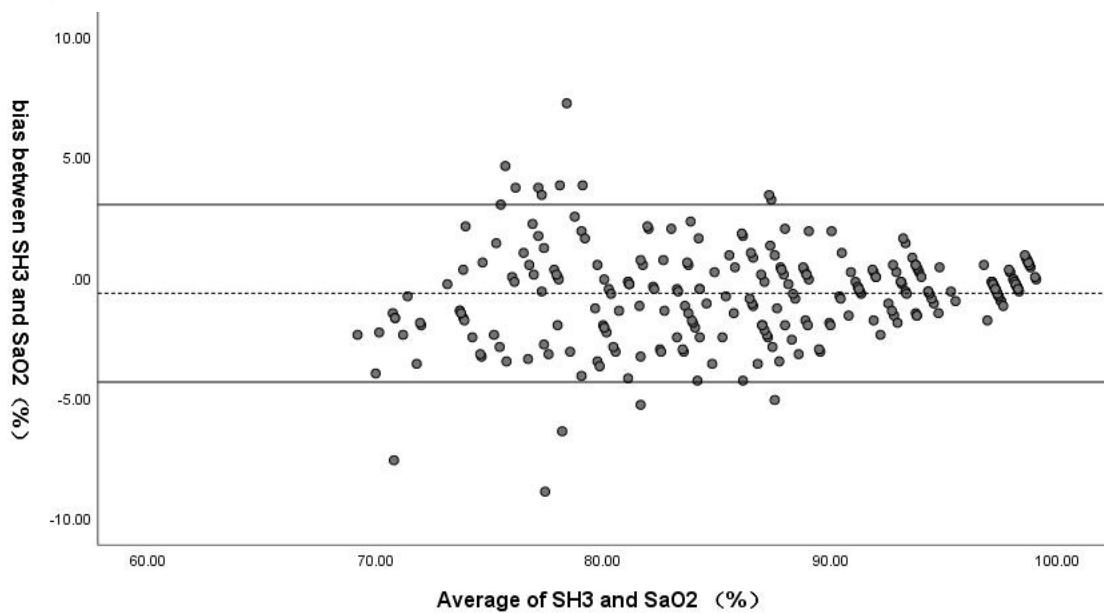
| SaO <sub>2</sub> Range | Arms     |          |          |          |            |               |
|------------------------|----------|----------|----------|----------|------------|---------------|
|                        | With SH1 | With SH3 | With SH4 | With SH5 | With SHD-A | With Ear Clip |
| 90%-100%               | 1.01     | 1.07     | 1.29     | 1.10     | 1.15       | 1.03          |
| 80%-90%                | 2.01     | 2.30     | 2.17     | 2.13     | 2.08       | 1.78          |
| 70%-80%                | 2.01     | 2.65     | 2.29     | 2.57     | 2.67       | 2.93          |
| 70%-100%               | 1.68     | 1.99     | 1.89     | 1.90     | 1.92       | 1.86          |

3. The figures below show the Bland-Altman Plot of SaO<sub>2</sub> vs SpO<sub>2</sub> measured using SH series sensor and ear clip sensor. In the plots, the upper and lower solid lines represent the upper and inferior limits of the 95% consistency, and the middle dotted line represents the average of the bias.

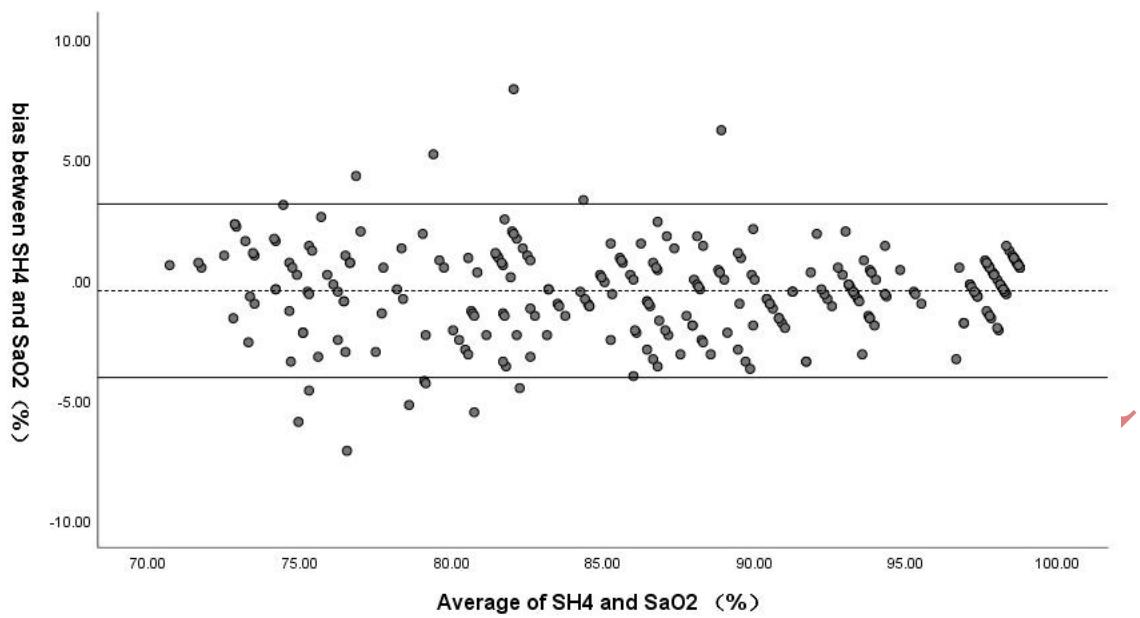
Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with SH1 sensor



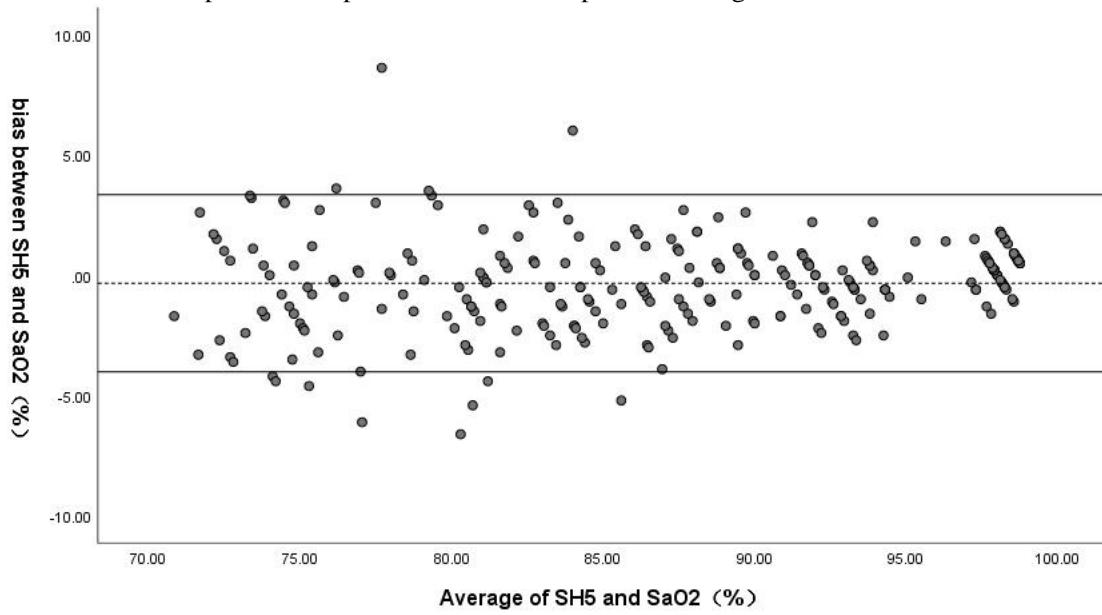
Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with SH3 sensor  
Average of SH1 and SaO<sub>2</sub> (%)



Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with SH4 sensor

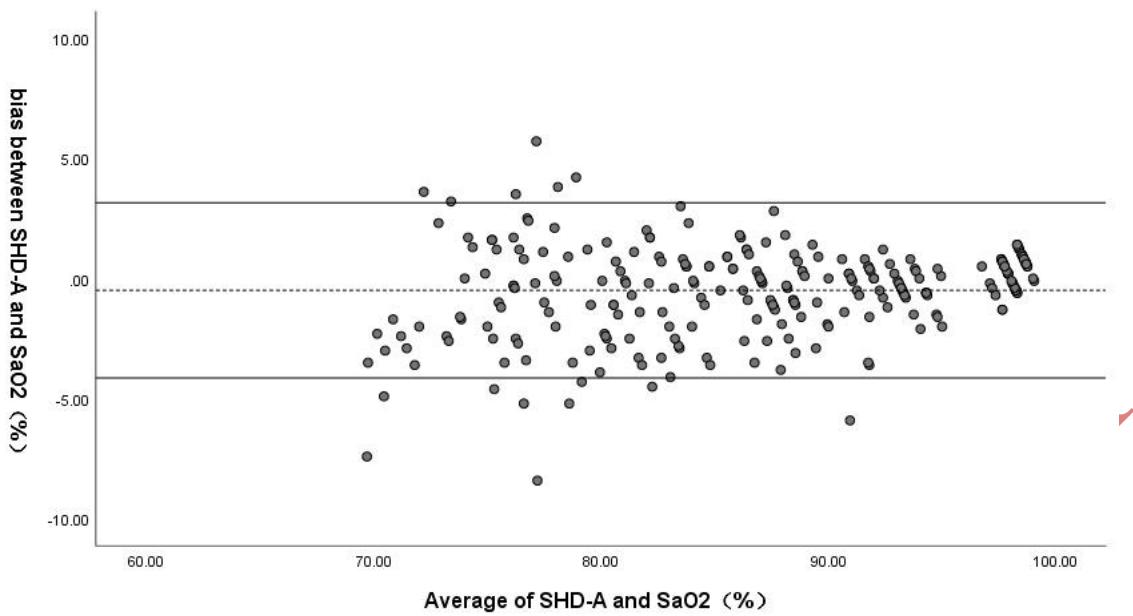


Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with SH5 sensor

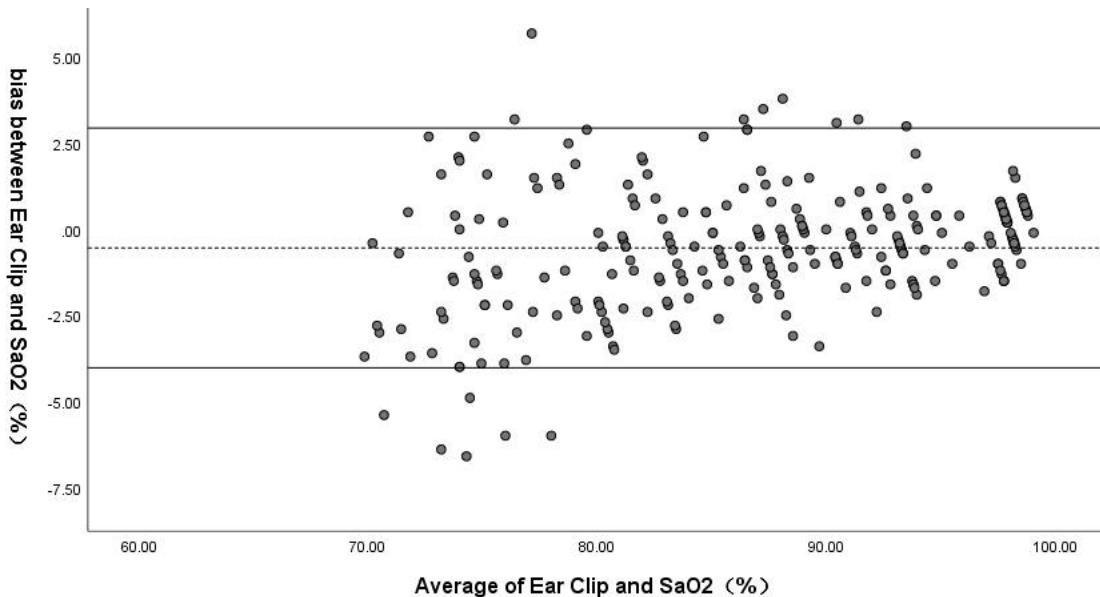


CO<sub>2</sub>

Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with SHD-A sensor



Bland-Altman plot for comparator's SaO<sub>2</sub> and SpO<sub>2</sub> of investigational device with ear clip sensor



## 12.9 SpO<sub>2</sub> Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.

2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

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# Chapter 13 Monitoring PR

## 13.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can obtain a pulse from any measured SpO<sub>2</sub> or any arterial pressure.

## 13.2 Setting PR Source

The monitor provides PR source options. Current pulse source is displayed in the PR parameter area. You can select SpO<sub>2</sub>, IBP (PA, ART, Ao, UAP, BAP, FAP, LV, P1-P4) or Auto as the PR source in the PR Setup > PR Source menu.

The PR Source menu displays the currently valid PR sources. When it is set to Auto, the monitor will automatically select the PR source by priority.

When the manually selected PR source is not available, the monitor automatically switches the PR Source to Auto. When the manually selected PR source is available, the monitor automatically switches back to the original PR source.

## 13.3 Pleth SQI

Pleth SQI refers to the credibility of the current PR value. The accuracy of the PR depends on the original signal for PR calculation. The better the signal quality, the higher the Pleth SQI. Pleth SQI is rated 1-10.

When PR source is SpO<sub>2</sub>, the Pleth SQI icon can be displayed in the interface.

## 13.4 Selecting PR Alarm Source

In most cases, the HR and PR numerics are identical. In order to avoid simultaneous alarms on HR and PR, the monitor uses either HR or PR as its active alarm source. To change the alarm source, select either ECG Setup > Alarm Source or PR Setup > Alarm Source, then select:

- HR: if you want HR to be the active alarm source.
- PR: if you select PR as the active alarm source. Be aware that if you select PR as the alarm source, ECG HR alarms are inactivated.
- Auto: If the alarm source is set to Auto, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is

switched on and valid HR values are available. The monitor will automatically switch to PR for the alarm source if:

- valid HR values can no longer be measured and
- a PR source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. If valid HR values become available again, the monitor automatically uses HR as alarm source.

When the manually selected alarm source is not available, the monitor automatically switches the Alarm Source to Auto. When the manually selected alarm source is available, the monitor automatically switches back to the original alarm source.

## Chapter 14 Monitoring NIBP

### 14.1 Overview

This monitor uses the oscillometric method for measuring NIBP.

iCUFS algorithm: Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

iFAST algorithm: During the cuff inflation, oscillometric devices detect the change of pulsation amplitude due to the cuff pressure change. The pulsations increase in amplitude and reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures. Oscillometric devices terminate the NIBP measurement and deflate quickly once the systolic pressure is determined.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2) in relation to mean error and standard deviation.

The invasive blood pressure is used to determine the adult, pediatric and neonate pressure in clinical investigation, and the arterial reference sites include umbilical artery, axillary artery, and radial artery. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine pregnant woman diastolic pressure.

When selecting the patient type on the patient admitting interface, it is recommended to choose Adult for patients greater than 21 years of age, Pediat for patients greater than 3 through 21 years of age and Neonat for patients from birth through 3 years of age.

## 14.2 NIBP Safety Information

### **WARNING**

- 1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
- 2 Do not measure NIBP on the arm of the same side with a mastectomy or lymph node clearance.
- 3 Use clinical judgement to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- 4 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- 5 Do not allow the cuff to cover the wound, or it may cause further injury.
- 6 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- 7 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
- 8 Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
- 9 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
- 10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
- 11 Continuous cuff pressure due to connection tubing kinking can block the blood flow and may result in injury to the patient.
- 12 Prolonged non-invasive blood pressure measurements in Auto, Continuous, or Sequence mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

### NOTE:

- 1 It is suggested that the user should not start NIBP measuring when the low

- battery displays, or the monitor may be turned off automatically.
- 2 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
  - 3 NIBP measurement can be affected by extremes of temperature, humidity and altitude.
  - 4 NIBP measurement value should be explained by qualified professionals.
  - 5 The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.
  - 6 The cumulative use time for the NIBP cuff in a single patient should be less than 30 days.
  - 7 NIBP measurement can be performed during electro-surgery and discharge of a defibrillator.
  - 8 Other factors that have been shown to result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.

### 14.3 NIBP Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- A regular arterial pressure pulse is hard to detect.
- Patients with cardiac arrhythmias.
- Patients with excessive and continuous movement such as shivering or convulsions.
- Patients with rapid blood pressure changes.
- Patients with severe shock or hypothermia that reduces blood flow to the peripheries.
- Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- Patients on an edematous extremity.

## 14.4 Measurement Modes

There are four NIBP measurement modes:

- Manual - measurement on demand.
- Auto - continually repeated measurements (between 1 and 480 minute adjustable interval). The interval can be user defined, and the default user defined interval is 30 minutes. After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval. When Clock is turned on and the measurement interval is set to 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 360 min and 480 min, the system will automatically adjust the next measurement time. For instance, if the measurement interval is set to 10 min, and NIBP auto measurement is started at 12:02, the next measurement will be taken at 12:10, and then at 12:20, 12:30, 12:40 and so on.
- STAT - the measurement will run consecutively at an interval of 5 s in five minutes. After a STAT measurement series, the monitor returns to the previous mode.
- Sequence - after the first measurement starts manually, NIBP measurements run automatically according to the preset times and interval. NIBP sequence measurement can have up to six phases. The measurement times and interval of each phase can be set individually. The measurement times can be set to Off, 1 to 30, and Continuous. When it is set to Off, sequence measurement will terminate in current phase, and no subsequent measurement phase will be performed. When it is set to Continuous, sequence measurement will continue in current phase, but no more subsequent measurement phase. The measurement interval can be set to 1-480 minutes.

## 14.5 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be observed:

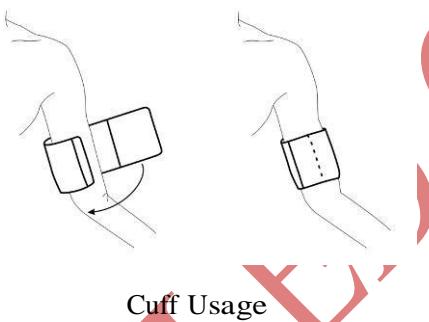
1. Ensure the patient position in normal use, including
  - ♦ Comfortably seated or lie flat, legs uncrossed;
  - ♦ Feet flat;
  - ♦ Back, elbow, forearm and feet supported;
  - ♦ Relax as much as possible, neither talking nor applying external pressure against the cuff. Rest for five minutes in a quiet environment.
2. Connect the cuff to the air tubing. Plug the air tubing to the NIBP connector on

the monitor.

Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below.

-Ensure that the cuff is completely deflated.

-Apply the appropriate size cuff to the patient (About the cuff size selection, please see Section NIBP accessories), and make sure that the symbol "Φ" is over the artery. The cuff shall be applied on the bare arm and there shall be no arm compression proximal to the cuff. Ensure that the middle of the cuff is at the level of the right atrium of the heart and the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.



3. Select the correct patient type setting for your patient in the Patient Info. menu.
4. Select a measurement mode in the NIBP Setup menu. See *Section Starting and Stopping NIBP Measurements for details*.
5. Press the  button on the front panel or shortcut key  on the main screen to start a measurement.
6. Wait until the first reading is taken.

**NOTE:**

- 1 The width of the cuff is either approximately 40% (50% for neonates) of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
- 2 If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

- 3 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 4 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.
- 5 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.
- 6 During the blood pressure measurement, if the user changes the patient type or updates the patient, the monitor will immediately terminate all measurements and clear the display of blood pressure parameters.

#### 14.5.1 Starting and Stopping NIBP Measurements

Start and stop NIBP measurement by selecting the hardkey on the front panel, shortcut key, or from the NIBP setup menu.

##### 1. Manual measurement

Access the NIBP Setup menu and set the Measure Mode item to Manual. Then press the  button on the front panel or shortcut key  on the main screen to start a manual measurement.

##### 2. Auto Measurement

Access the NIBP Setup menu and set the Measure Mode item to Auto, select time interval as need, then press the  button on the front panel or shortcut key  on the main screen.

##### 3. STAT measurement

Select the shortcut key  or access the NIBP Setup menu and pick the Continuous item to start a continuous measurement. The STAT measurement will last 5 minutes.

##### 4. Sequence measurement

Access the NIBP Setup menu and set the Measure Mode item to Sequence. Access the Sequence Measure Set dialog to set the Phase, Times and Interval. Then press the  button on the front panel or shortcut key  on the main screen to start the measurement.

## 5. Stopping the measurement

During the measurement, press the  button on the front panel or shortcut key ,  on the main screen at any time to stop measurement.

## 14.6 NIBP Setup

Select the NIBP parameter area to access the NIBP Setup menu.

### 14.6.1 Setting Alarm Limit Display

Select NIBP Setup > Alarm Limit Display Format to set whether to display the alarm limits of diastolic NIBP and mean NIBP. SYS and SYS&DIA&MAP are optional. The default setting is SYS.

### 14.6.2 Setting Inflation Value

To change the inflation value:

1. Select Inflation Value in NIBP Setup menu;
2. Choose the appropriate setting from the pull-down list. If Auto is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

### 14.6.3 Displaying/Hiding PR

The user can set whether to display the PR value in the NIBP parameter area.

To display PR, enable Display PR in the NIBP Setup menu.

### 14.6.4 Setting NIBP End Tone

The monitor can issue a reminder tone at the completion of NIBP measurement.

To set the NIBP end tone, in the NIBP Setup menu, select the appropriate volume for the NIBP End Tone. The volume ranges from 0 to 10. If it is set to 0, the NIBP end tone will be off.

### 14.6.5 Setting NIBP Trigger Recording

To set the NIBP to trigger recording, enable NIBP Trigger Recording in the NIBP Setup menu. The monitor triggers recording at the completion of NIBP measurement.

## 14.7 Selecting NIBP Algorithm

The EDAN NIBP module supports two measurement algorithms: iCUFS and iFAST. iCUFS measurement is applicable to adults, pediatrics and neonates. iFAST measurement shortens the blood pressure measurement time and rapidly outputs values, which is applicable to adults and pediatrics. iFAST and iCUFS are also intended for use with pregnant, including pre-eclamptic patients.

To set the NIBP algorithm, select Menu > System > User Maintain > Parameter Maintain > NIBP and set NIBP Algorithm to iCUFS or iFAST.

## 14.8 Manometer Mode

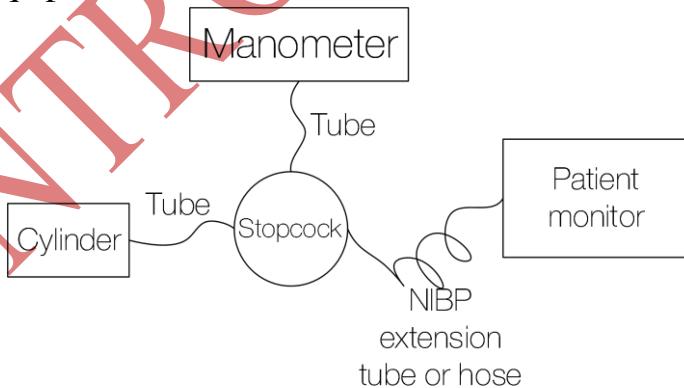
Manometer mode verifies accuracy of the NIBP system.

**NOTE:** The manometer test is used to verify the measurement accuracy only and will not affect the measurement results.

Tools required: stopcock, NIBP extension tubes, cylinder (200 ml), manometer (measurement range should be within 0 to 300 mmHg; accuracy should be within  $\pm 0.3$  mmHg.)

Procedure:

1. To conduct the NIBP accuracy test, access the User Maintain menu through the following sequence: Menu > System > User Maintain > Parameter Maintain > NIBP.
2. Connect the equipment as shown below.



3. Select Manometer Mode.
4. Simulate a fixed static pressure on the monitor using a manometer.
5. Wait 10 seconds until the pressure stabilizes. Verify the displayed values on the monitor against the manometer setting.
6. A tolerance of  $\pm 3$  mmHg is allowable.

## 14.9 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, pick Reset in the Menu > System > User Maintain > Parameter Maintain > NIBP menu to activate self-test procedure, and thus restore the system from abnormal performance.

## 14.10 Calibrating NIBP

NIBP calibration is not performed by the user. Cuff-pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional. See the *Service Manual* for details.

## 14.11 Leakage Test

Leakage test is used to detect the air tightness of the NIBP pump, valve, and trachea. If the test fails, the system will display NIBP leakage. NIBP leak detection should be performed at least once every two years or when you think the measurement is inaccurate.

### WARNING

This leakage test other than being specified in the ISO 81060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

### Procedure of Leakage Test

1. Connect the cuff securely with the socket for NIBP air hole.
2. Wrap the cuff around the cylinder of an appropriate size, do not wrap the cuff around limbs.
3. Make sure the patient type has been set to Adult.
4. Access Menu > System > User Maintain > Parameter Maintain > NIBP > Leakage Test.
5. Select Start. Then the prompt Leak. Test Running will appear indicating that the system has started the leakage test.

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system

will automatically open the deflating valve to stop the leak test and indicates NIBP Leak. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

6. If the alarm information NIBP Leak appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

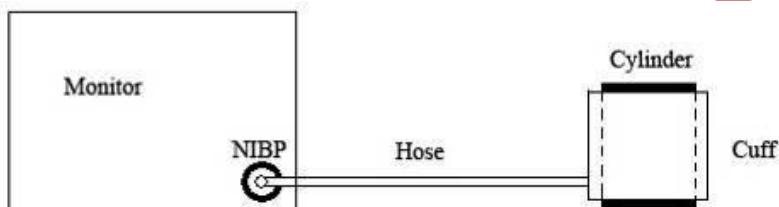


Diagram of NIBP Air Leakage Test

#### 14.12 Assisting Venipuncture

The user can use the NIBP cuff to cause a pressure close to diastolic pressure, so as to block the venous blood vessel and therefore help venipuncture. To assist venipuncture:

1. Select NIBP Setup > Venipuncture;
2. Select the appropriate Cuff Pressure according to the patient type;
3. Select Start, the monitor displays: Venipuncture Starting.
4. Wait until the monitor prompts Venipuncture. If an abnormal alarm occurs before it, no follow-up operation can be carried out. Restart the procedure after checking if necessary;
5. Puncture vein and draw blood sample;
6. Select Stop to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates when the venipuncture time expires (170 seconds for adult and pediatric patient, 85 seconds for neonatal patient).

During the venipuncture, pay attention to the cuff pressure and the countdown displayed in the NIBP numerics area. When the remaining time is 30 seconds, the

monitor issues a reminder tone and the countdown displays in red, prompting the user that the venipuncture time is to expire.

NOTE:

When the monitor is in DEMO mode, privacy mode, standby mode, continuous measurement process, manual measurement process, sequence measurement process or auto measurement process, Assisting Venipuncture function is not available.

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## Chapter 15 Monitoring TEMP

### 15.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin, oral cavity or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values and get the temperature difference. T1 or T2 can be switched on/off separately and will not be affected by each other.

### 15.2 TEMP Safety Information

#### WARNING

- 1 Verify probe cables fault detection before the beginning of monitoring phase.  
Unplug the temperature probe cable of the channel 1 from the socket, and then the screen will display the error message TEMP T1 Sensor OFF and the auditory alarm is activated. It is the same to the other channel.
- 2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
- 3 Temperature probes do not need any probe covers; Please remember to clean and disinfect the probe before and after each use on a patient.

#### NOTE:

- 1 The reference body site temperature is the same as the temperature of the measuring site.
- 2 The cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

### 15.3 Making a TEMP Measurement

1. Select an appropriate probe for your patient.
2. Plug the probe to the temperature connector.
3. Attach the probe to the patient.
  - ♦ For skin temperature probe: Dry skin completely in area of intended probe

placement. Fasten the probe with medical tape and place the sensor over dry skin.

- ◆ For oral temperature probe: Place the probe tip under patient's tongue on either side of the mouth to reach the sublingual pocket. Close the patient's lips and allow breathing from the nose.
- ◆ For rectal temperature probe: Ensure that the patient is in lateral position, prone position, or dorsal recumbent position, and expose the temperature measurement site. Lubricate the temperature probe prior to insertion, and place the probe in accordance with currently acceptable medical procedures.

4. Select TEMP sensor type and label before measuring if necessary.
5. Check that the alarm settings are appropriate.
6. It takes 5 minutes for the temperature measurement to stabilize.
7. During surgical procedures which employ electro-cautery, use currently acceptable procedures to minimize conditions of the thermistor and a lead wire functioning as an alternate path for radio-frequency current to return to ground, causing localized tissue burns. Procedures which may minimize risk of electro-surgical burns are:
  - ◆ Keep both active and ground electrodes of the electro-cautery system in close proximity so that the skin temperature sensor is outside of the radio-frequency current field.
  - ◆ Keep the monitor with its associated cables separated from electrocautery systems.

#### PRECAUTION

- 1 Sweat will lead to increased heat dissipation, affecting the measurement accuracy. Dry the skin thoroughly. Shave hair from sites, if necessary.
- 2 Do not measure rectal temperature on patients with rectal or anal surgery, or diarrhea.
- 3 Patients with myocardial infarction should not have their temperature measured rectally to avoid stimulating the anus and causing the vasovagal reflex, leading to bradycardia.
- 4 For long-term monitoring, periodically check surrounding skin of application site according to the patient's condition and change the application site if required.

**PRECAUTION**

- 5 When used in conjunction with electrocautery systems, large variations in temperature readings may occur occasionally.

NOTE:

- 1 Choose a medical tape which is coated with medical grade hypoallergenic adhesive suitable for skin application according to the patient needs.
- 2 Do not measure axillary temperature on patients with skin damage, surgery, inflammation, excessive sweat in the axilla, and shoulder joint injury.
- 3 When using these probes, follow standard application practices recommended by your medical facility.
- 4 To avoid patient injury:
  - ◆ Do not apply these temperature probes to patients who are undergoing Magnetic Resonance Imaging (MRI) procedures.
  - ◆ Always use caution when applying, inserting, or removing a temperature probe from a patient.
  - ◆ Assure that probe and connector cable are not positioned where they could inhibit circulation in extremities, become entangled around patient, or cause choking, strangulation.

#### 15.4 Selecting TEMP Sensor Type

The user can choose the TEMP sensor type as the temperature signal source.

To configure the TEMP sensor type, select Menu > System > User Maintain > Parameter Maintain > TEMP, and set Probe Type to YSI-10K or YSI-2.252K.

#### 15.5 Selecting a Temperature for Monitoring

Select the temperature label according to the measurement site. The label is a unique identifier for each type of temperature.

To select the label,

1. Click the TEMP parameter area to enter TEMP Setup menu.
2. Select the appropriate label from the list for T1 and T2.

| Label | Description             |
|-------|-------------------------|
| Tskin | Skin temperature        |
| Trect | Rectal/Oral temperature |

## 15.6 Calculating Temp Difference

The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

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## Chapter 16 Monitoring IBP (Optional)

### 16.1 Overview

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display.

The monitor measures direct blood pressure of one selected blood vessel through two channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

### 16.2 IBP Safety Information

#### WARNING

- 1 The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.
- 2 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
- 3 Disposable IBP transducer or domes should not be reused.
- 4 If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.
- 5 All invasive procedures have risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
- 6 Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero and calibration, and then cause erroneous readings.
- 7 The longest duration of IBP arterial catheterization is 7 days.

#### NOTE:

- 1 Use only the pressure transducer listed in the IBP Accessories.
- 2 If measuring intracranial pressure (ICP) on a sitting patient, adjust the transducer on the same level with the top of the patient's ear. Incorrect

- leveling may lead incorrect values.
- 3 Confirm you set correct alarm limit for labels, the alarm limit you set are stored for its label only. Changing label may change the alarm limit.
  - 4 Don't perform IBP calibration when a patient is being monitored.
  - 5 When using high frequency ventilation, make sure that the ventilator catheter is not connected to or indirectly connected to the arterial catheter at zero pressure. This can lead to less pressure variations, thus interfere the zeroing process.
  - 6 Please use the accessory of the same model from the same manufacturer.
  - 7 Zeroing or and calibration are required after replacing the transducer or cable.

### 16.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the IBP socket and switch on the monitor.
2. Prepare the flush solution.
3. Flush through the system, exhaust all air from the tube, and ensure that the transducer and stopcocks are free of air bubbles.
4. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
5. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
6. For the label name selection, please see *Selecting the Pressure Label*.
7. To zero the transducer, please see *Zeroing the Pressure Transducer*.

#### WARNING

If there are air bubbles in the tube system, you should flush the system with the solution again. The bubbles may cause erroneous pressure readings.

#### 16.3.1 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

- When you use a new transducer or tubing;

- Every time you reconnect the transducer cable to the monitor;
- If you think the monitor's pressure readings are not correct.

When using a pressure module, the zero information is stored in the module.

The zeroing procedure is listed as below:

1. Turn off the stopcock to the patient.
2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.
3. Select the shortcut key  or the IBP Setup menu, select Zero > Zero XX or Zero All. (XX stands for the IBP label name). After confirmation, the user can zero the pressure of certain channel or pressure of all channels. After zeroing, the interface displays the result and last calibration time.
4. When you see the message Zero Ok, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

### 16.3.2 Troubleshooting the Pressure Zeroing (Taking Art for Example)

| Message                            | Corrective Action  |
|------------------------------------|--|
| Sensor Off, Unable to Zero         | Make sure that transducer is not off, and then proceed zeroing.  |
| Unable to Zero in Demo Mode        | Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.                         |
| Pressure Overrange, Unable to Zero | Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician. |
| Pressure Pulsating, Unable to Zero | Make sure that the transducer is vented to air, not connected to a patient, and try again.                       |

### 16.3.3 IBP Calibration

IBP is not user-calibrated. Calibration should be performed by a qualified service professional as frequently as dictated by your Hospital Procedures Policy.

## 16.4 IBP Setup

Select the parameter area or waveform area of any pressure to access the IBP Setup menu.

### 16.4.1 Selecting the Pressure Label

Tell the monitor which pressure you want to monitor by selecting its pressure label. The label is a unique identifier for each type of pressure. When you choose a label, the monitor uses that label's stored settings, for example color, wave scale and alarm settings. The label also determines which algorithm is used to process the pressure signal, so an incorrect label can lead to incorrect pressure values. To select the label:

1. Select Alias in the IBP Setup menu.
2. Select the appropriate pressure label from the list.

| Label | Description                 | Label | Description                              |
|-------|-----------------------------|-------|--|
| Art   | Arterial blood pressure     | ICP   | Intracranial pressure                    |
| Ao    | Aortic pressure             | LAP   | Left atrial pressure                     |
| PA    | Pulmonary artery pressure   | RAP   | Right atrial pressure                    |
| BAP   | Brachial arterial pressure  | LV    | Left ventricular pressure                |
| UAP   | Umbilical arterial pressure | UVP   | Umbilical venous pressure                |
| FAP   | Femoral arterial pressure   | P1-P4 | Alternative non-specific pressure labels |
| CVP   | Central venous pressure     | CPP   | Cerebral perfusion pressure              |

If the current pressure is non-specific pressure (P1, P2, P3 or P4), set the Pressure Type to Artery or Vein in the IBP Setup menu. The default setting is Artery.

For the arterial pressure, its corresponding parameter area displays systolic pressure, diastolic pressure and mean pressure; for the venous pressure, its corresponding parameter area only displays the mean pressure.

NOTE: The pressure type option is only valid when the label is P1-P4 and does not take effect under other labels.

### 16.4.2 Setting Alarm Limit Display

Set the Alarm Limit Display Format in the IBP Setup menu.

- If the current pressure is arterial pressure, the display format of the alarm limits can be set to SYS or SYS&DIA&MAP. The default setting is SYS.
- If the current pressure is venous pressure, the display format of the alarm limits is fixed to MAP and cannot be set.

### 16.4.3 Setting IBP Filter

1. Access Menu > System > User Maintain > Parameter Maintain > IBP.

2. Set the IBP Filter to 12.5 Hz or 40 Hz. The default setting is 12.5 Hz.

#### 16.4.4 Setting the IBP Waveform Speed

To change the speed, choose Speed and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

#### 16.4.5 Changing the IBP Waveform Scale

The top and bottom rulers are available for each channel of IBP waveform. Choose Scale and select a suitable setting from the pop-up list. If Customized is selected, adjust the top and bottom rulers manually.

### 16.5 Calculating CPP

CPP is calculated by subtracting MAP and ICP, it means:  $CPP = MAP - ICP$ .

To select an arterial pressure as CPP source:

1. Click the ICP parameter area to enter into ICP Setup interface.
2. Select CPP Source; CPP source can be selected as Auto, Art, Ao, FAP, LV, UAP, BAP, P1, P2, P3 or P4.

Only when P1, P2, P3 and P4 are arterial pressure can they be selected as CPP source.

### 16.6 Calculating PPV

Pulse Pressure Variation (PPV) is calculated from the specific arterial pressure values, which reflects the variation between the maximal pulse pressure and the minimum pulse pressure in 30 seconds. Pulse pressure is affected by left ventricular-stroke volume, arterial resistance and arterial compliance.

#### WARNING

- 1 The clinical value of the derived PPV information must be determined by a physician. According to recent scientific literature, the PPV information is restricted to sedated patients who receive controlled mechanical ventilation and without arrhythmia. Whether the calculation results in other situations are clinically significant, applicable and reliable must be determined by a physician.

**WARNING**

2 In below situations, the calculated PPV value may be inaccurate:

- the respiration rate is lower than 8 rpm
- the tidal volume during ventilation is lower than 8 ml/kg
- patients have acute right ventricular functional disorder (pulmonary heart disease)

3 PPV measurement has been validated only for adult patients.

PPV is calculated according to the following equation:

$$\text{PPV} = (\text{PPmax} - \text{PPmin}) / (\text{PPmax} + \text{PPmin}) / 2 * 100\%$$

To select an arterial pressure as PPV source:

1. Click the PPV parameter area to enter PPV Setup menu.
2. Select PPV Source; PPV source can be selected as Auto, Art, Ao, FAP, LV, UAP, BAP, P1, P2, P3 or P4.

Only when P1, P2, P3 and P4 are arterial pressure can they be selected as PPV source.

## 16.7 Calculating SVV

Stroke Volume Variation (SVV) is the percentage of the difference between maximum stroke volume and minimum stroke volume and the ratio of average stroke volume in the specified time. The main principle is the effect of respiratory movement on cardiac pump blood. SVV is only applicable in patients on controlled mechanical ventilation.

SVV is calculated according to the following equation:

$$\text{SVV} = (\text{SVmax} - \text{SVmin}) / \text{SVmean} * 100\%$$

To select an arterial pressure as SVV source:

1. Click the SVV parameter area to enter SVV Setup menu.
2. Select SVV Source; SVV source can be selected as Auto, Art, Ao, FAP, LV, UAP, BAP, P1, P2, P3 or P4.

Only when P1, P2, P3 and P4 are arterial pressure can they be selected as SVV source.

## 16.8 Measuring PAWP

PAWP, Pulmonary Artery Wedge Pressure, used to assess the cardiac function, is obtained by introducing a balloon-tipped pulmonary artery flotation catheter into the pulmonary artery. When the catheter is in one of the smaller pulmonary arteries, the

inflated balloon occludes the artery allowing the monitor to record changes in the intrathoracic pressures that occur throughout the respiration cycle.

### 16.8.1 Measurement Procedures

Pulmonary Artery Wedge Pressure (PAWP) values are affected by fluid status, myocardial contractility, valve and pulmonary circulation integrity. The most accurate PAWP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant. You can use the respiration waveform as a reference when assessing the PAWP waveform, to ensure constant measurement timing relative to the respiratory cycle.

To start the measurement:

1. On the standard screen interface, select the PA parameter window to enter its setup menu. Then, select PAWP to open the PAWP screen.
2. Prepare and check the accessories according to your hospital policy.
3. Select Measure.
4. Inflate the balloon and pay attention to PA waveform changes on the screen.
5. After obtaining a stable PAWP waveform, press Freeze to freeze the waveform. In freeze status, adjust the PAWP scale to an appropriate position by moving the cursors up and down according to the clinical experience. Select Save to store the PAWP, CVP, HR values. Select Average to obtain the average values of PAWP. To review the stored PAWP, CVP, HR values, select Review.
6. Deflate the balloon when the monitor prompts you “Please deflate the balloon!”.
7. To start a new measurement, select Remeasure.

#### WARNING

- 1 Prolonged inflation can cause pulmonary hemorrhage, infarction or both. Inflate the balloon for the minimum time necessary to get an accurate measurement.
- 2 If the PAWP (mean) is greater than the PA (systolic), deflate the balloon and report the incident in accordance with hospital policy, because the pulmonary artery could be accidentally ruptured, and the PAWP value derived will not reflect the patient's hemodynamic state, but will merely reflect the pressure in the catheter or balloon.

**WARNING**

- 3 The pressure receiver in the catheter records the pressure change that occurs only at the front of the obstruction.
- 4 Due to the short measurement delay, do not use sidestream CO<sub>2</sub> as a direct reference to determine the end point of the breath in the pressure curve.
- 5 If the balloon is not inflated but the pulmonary artery floating catheter enters the wedge position, the pulmonary artery pressure waveform becomes wedge-shaped. Follow the standard steps to take appropriate action to correct this situation.
- 6 PAWP measurement is not applicable to neonate patients.
- 7 When entering the PAWP interface, the monitor automatically turns off the PA alarm.

#### 16.8.2 Setting the Waveforms of the PAWP Screen

On the the PAWP screen, select Setup to access the PAWP setup menu:

- View Reference Waveform 1, ECG waveform served as the first reference waveform.
- View Reference Waveform 2, RESP waveform served as the second reference waveform.
- Set Speed to an appropriate value from the pop-up list.
- Choose Scale and select the appropriate setting from the pop-up list.
- Select a suitable ruler for the displayed waveforms from the options Top Ruler and Bottom Ruler.

## Chapter 17 Monitoring C.O. (Optional)

### 17.1 Overview

The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters by using the Thermodilution method. The Thermodilution method is to inject a cold solution into the blood circulation system and measure the temperature changes caused by the cold solution through the thermistor of the pulmonary artery floating catheter, and the C.O. value is calculated by using the temperature dilution curve. C.O. measurement is applicable for adults only.

### 17.2 C.O. Safety Information

#### WARNING

- 1 Make sure that appurtenance applied is in conformity with relevant Medical Device Safety Requirements.
- 2 Accessories should be avoided from contact with conductive metal body when being connected or applied.
- 3 All invasive procedures involve risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
- 4 The C.O. measurement results may be incorrect during electrosurgery.
- 5 C.O. floating catheter shall be removed or reinserted after 3 days.

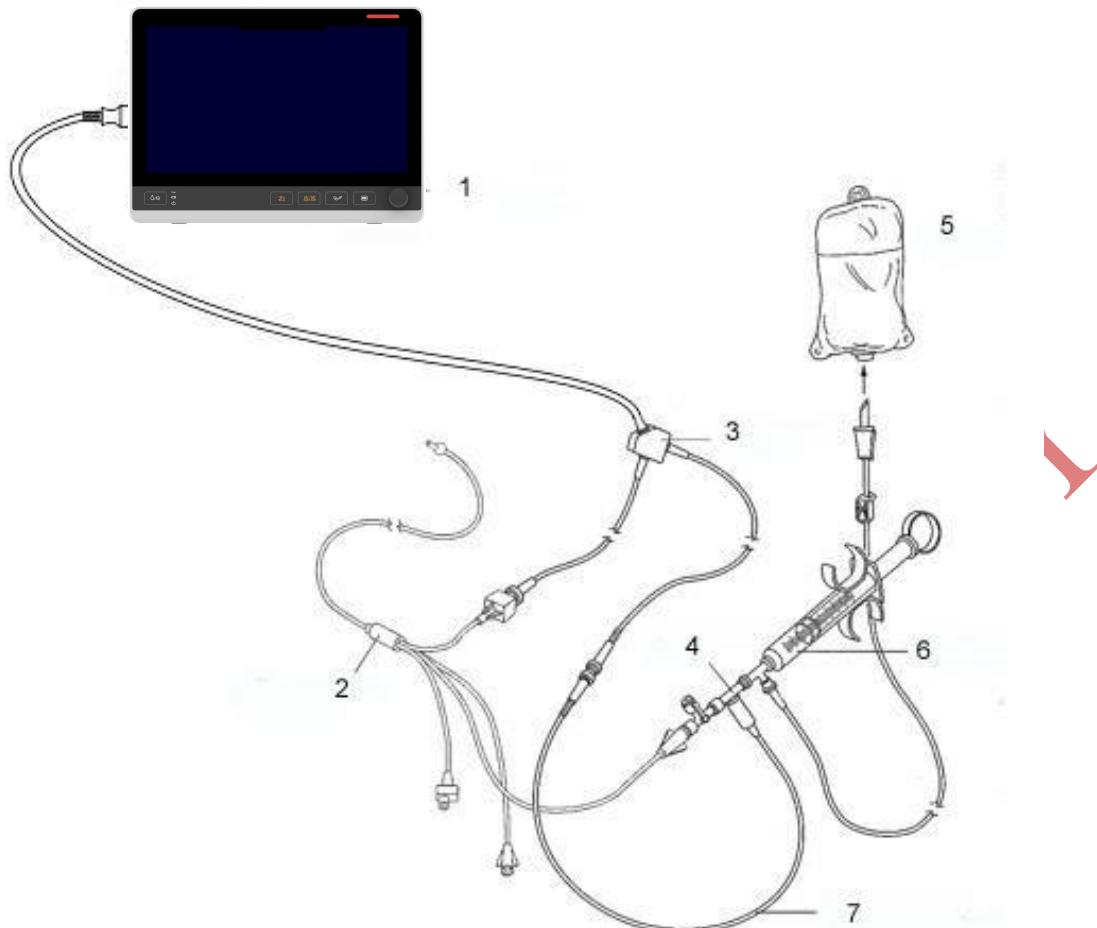
#### NOTE:

- 1 To replace the catheter thermistor, please enter the catheter computation coefficient into the Constant item according to the instruction.
- 2 Please start C.O. measurement after blood temperature is stable, otherwise the measurement may fail.

### 17.3 C.O. Monitoring

#### Preparing Measurement

1. Plug the C.O. cable into the C.O. socket and turn on the monitor.
2. Attach the injective probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable.



1: Monitor; 2: Thermodilution Catheter; 3: Cardiac Output Cable; 4: Injectate Sensor Housing; 5: Injectate; 6: Delivery System; 7: In-line injectate Temperature probe.

#### C.O. Sensor Connection

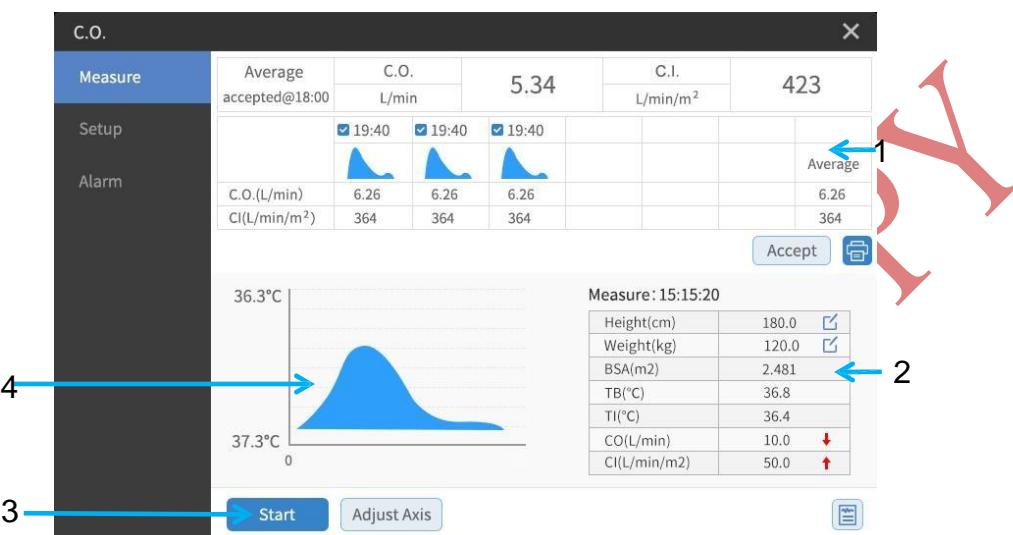
3. Open the patient information window to confirm the patients' height and weight.
4. Select Menu > System > User Maintain and input user maintenance password > Parameter Maintain > C.O.. Check that the correct computation constant is entered.
- The computation constant is associated with catheter and injectate volume. When the catheter is changed, please adjust Constant based on product description provided by the manufacturer. After user's confirmation, the setup takes effect.
5. Select the C.O. parameter area to enter the C.O. Setup menu. In C.O. Setup menu, set:
  - Inj. Temp Source: Select Auto or Manual from the list, when set as Manual, the system directly displays the injectate temperature from INJ. TEMP. Ensure INJ. TEMP is correct, otherwise the C.O. measurement may be affected. When set as Auto, the system obtains the injectate temperature through sampling.

NOTE: The cardiac output is calculated based on the injection temperature source

at the end of the measurement, so do not change the injection temperature source before the measurement is completed.

### Performing C.O. Measurement

- Select the shortcut key  or pick the Measure item in the C.O. dialog. The C.O. Measure menu displays as below:



- 1 Historical measurement values and average value
- 2 Current measurement values
- 3 Functional keys
- 4 Current measurement curves

The functional keys on the C.O. measure window are explained in the following table:

|   |   |
|---|---|
| Start   | Start a measurement.  |
| Cancel  | Cancel the processing measurement or cancel the result after measurement. |
| Accept  | Accept the average values of C.O. and CI.                                 |
| Adjust Axis   | Adjust the X axis and Y axis.   |
|  | Print out the measurement result through the recorder.                    |

2. Press the Start button, and then start injection. The thermodilution curve, current blood temperature and the injective temperature are displayed during the measurement. Curve drawing will stop automatically when the measurement finishes, and the C.O. and CI will be calculated and displayed on the screen.

To ensure the accuracy of the measurement, it is suggested that a reasonable interval should take place between two consecutive measurements. The Interval can be set in the C.O. Setup menu (adjustable range: 5 to 300 seconds). The interval time counter is displayed on the screen. The next measurement cannot be performed until the time reduces to zero.

A maximum of six measurements can be saved. If performing additional measurements, the earliest measurement will be automatically deleted when a seventh curve is saved.

In C.O. review window, select required curves from the 6 measurement curves, and the monitor will automatically calculate and respectively display the average values of C.O. and CI.

#### WARNING

- 1 Make sure that the computational constant for the measurement is appropriate to the catheter used.
- 2 Before a C.O. measurement is initiated, check the accuracy of patient setup. The calculation of C.O. is related to the patient height, weight, and catheter computation coefficient; therefore, incorrect input will lead to error in calculation.

#### NOTE:

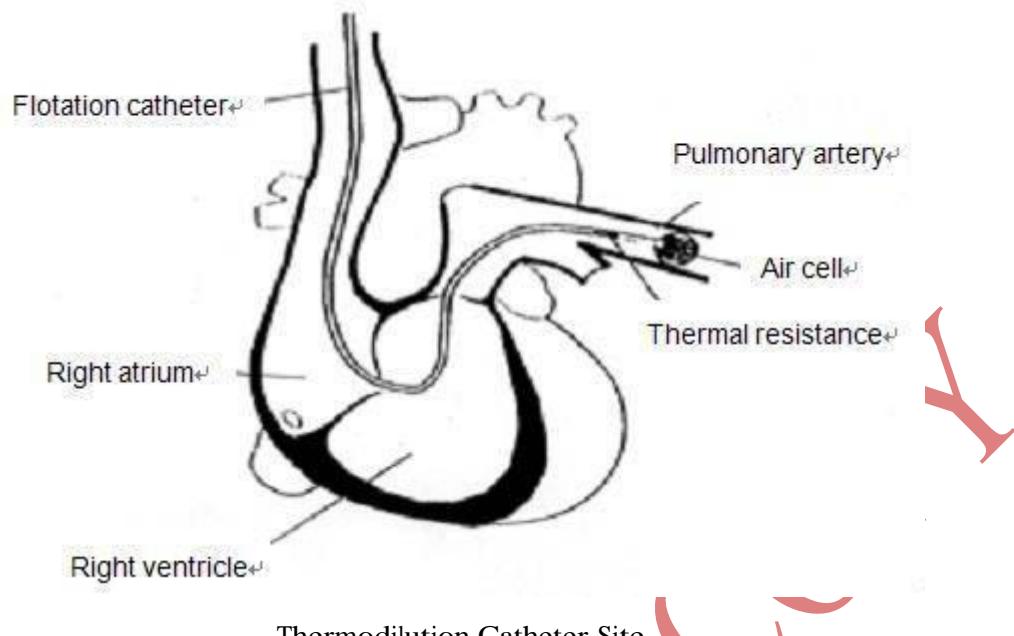
- 1 The blood temperature alarm will not function during C.O. measurement. It will resume automatically when the measurement is over.
- 2 Please inject as soon as possible after pressing Start, and complete each injection within 4 to 5 seconds.
- 3 It is strongly recommended that you wait at least one minute (or longer depending on the patient's clinical condition) before starting the next measurement.

### 17.4 Blood Temperature Monitoring

Blood temperature monitoring can function when C.O. measurement is not taken. The blood temperature is measured by the thermistor situated in the distal end of the flotation catheter in the pulmonary artery.

The blood temperature alarm function will not work during the C.O. measurement. When the measurement ends, the function will automatically resume.

The current blood temperature is displayed in the C.O. parameter area.



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## Chapter 18 Monitoring CO<sub>2</sub> (Optional)

### 18.1 Overview

The monitor provides the sidestream method for CO<sub>2</sub> monitoring. EDAN etCO<sub>2</sub> module, is used for sidestream measuring.

The principle of CO<sub>2</sub> measurement is primarily based on the fact that CO<sub>2</sub> molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO<sub>2</sub> concentration of patient sample, the CO<sub>2</sub> concentration will compute according to the detecting CO<sub>2</sub> absorption intensity of patient sample.

Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a CO<sub>2</sub> sensor. You can measure Sidestream CO<sub>2</sub> using the monitor's built-in CO<sub>2</sub> measurement. Respiration rate is calculated by measuring the time interval between detected breaths.

### 18.2 CO<sub>2</sub> Safety Information

#### WARNING

- 1 Do not use the device in the environment with flammable anesthetic gas, such as anesthetic mixed with air, oxygen, or nitrous oxide. Otherwise, there is an explosion hazard.
- 2 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO<sub>2</sub> measurement.
- 3 The accuracy of the CO<sub>2</sub> measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.
- 4 The monitor will be damaged if any pipeline from the CO<sub>2</sub> module's air tube /the air inlet /the air outlet is plugged by water or other materials.
- 5 Using high-frequency electrosurgical units may increase the risk of skin burn. In this case, do not use antistatic or conductive respiratory tubing.
- 6 Squeezing or bending the sampling line during sidestream CO<sub>2</sub> measurement may cause inaccurate CO<sub>2</sub> readings or no reading.
- 7 When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause incorrect measurement result.

**WARNING**

- 8 Leakage in the respiratory system or sampling system may result in a significant low display of the etCO<sub>2</sub> value. Always keep all components connected firmly and check for leaks according to standard clinical procedures.
- 9 The etCO<sub>2</sub> reading is not always closely related to the paCO<sub>2</sub> value, especially in neonatal patients, and patients with pulmonary disease, with pulmonary embolism or inappropriate ventilation.
- 10 Do not measure CO<sub>2</sub> while nebulized medications are being delivered.
- 11 The CO<sub>2</sub> module temporally stops measuring during zeroing.
- 12 Do not use the etCO<sub>2</sub> monitor for diagnostic purpose.
- 13 CO<sub>2</sub> No Breath Detected alarm is based on detection of breaths within a configured time frame.
- 14 CO<sub>2</sub> No Breath Detected alarm should not be used or relied upon while the patient is unattended.
- 15 Only one CO<sub>2</sub> measurement parameter is supported at a time.
- 16 Incorrect placement of a nasal cannula or use of a breathing mask can result in a lower etCO<sub>2</sub> reading than the actual value.
- 17 Do not use the adult or pediatric nasal sampling line with a neonatal patient. Otherwise, patient injury could result.

**PRECAUTION**

- 1 The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.
- 2 When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact the service staff of the manufacturer.
- 3 To prevent the module from abnormal work, please ensure the water trap detection button is not mistakenly touched.
- 4 Please replace and discard the water trap when blocking. Do not reuse it, otherwise the reading is not accurate and even the device may be damaged.

**PRECAUTION**

- 5 Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 90 hours with the flowrate of 100 ml/min, approximately 130 hours with the flowrate of 70 ml/min, and approximately 180 hours with the flowrate of 50 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.
- 6 The sample gas flowrate 50 ml/min is only applicable to patients whose respiratory rate ranges from 0 rpm to 40 rpm.
- 7 etCO<sub>2</sub> values measured from the CO<sub>2</sub> module may differ from those from the blood gas analysis.

**NOTE:**

- 1 Disconnect the water trap from the holder or set Work Mode to Standby when the module is not in use. Setting path: CO<sub>2</sub> Setup > Work Mode > Standby.
- 2 To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.
- 3 After the low battery alarm appears, please do not start the CO<sub>2</sub> measurement, or the monitor may turn off for the low capacity of battery.
- 4 For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.
- 5 If the measurement or sensor fails, stop measurement before the qualified service personnel solves the problem.
- 6 The cumulative use time for the sampling line in a single patient should be less than 30 days.
- 7 When cyclical pressure reaches 10 Kpa, the gas accuracy will be affected.
- 8 Always keep the end connecting to the sampling line in an upright position when placing the airway adapter. This will prevent condensate water from entering the sampling line and causing occlusion.
- 9 Place the connector of adapter and sampling line as close to the patient as possible.

- 10 EDAN etCO<sub>2</sub> module is equipped with automatic air pressure compensation, and manual setting is not required.

## 18.3 Monitoring Procedures

### 18.3.1 Zeroing

EDAN etCO<sub>2</sub> module itself has automatic zero function, only when the measurement is abnormal or measurement results are doubtful, the user can perform manual zero as following steps:

1. Wait until the monitor's warm-up message disappears; keep the monitor away from CO<sub>2</sub> source and in a well-ventilated environment.
2. In the CO<sub>2</sub> Setup menu, set Work Mode to Measure.
3. Select Zero Calibration in CO<sub>2</sub> Setup menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO<sub>2</sub> monitoring can be performed.

NOTE: The Auto Zero shall be suppressed for 5 min when physiological/technical alarms related to EDAN etCO<sub>2</sub> module are active.

### 18.3.2 Hiding the Invalid Display after Zeroing the CO<sub>2</sub> Module

Within 30 s after the zero calibration starts, the monitor displays Zero Recovering and invalid CO<sub>2</sub> value. Valid data will reappear 30 seconds after the zero calibration is started. The user can hide the display of Zero Recovering and show CO<sub>2</sub> values. To hide the display of Zero Recovering, follow these steps:

1. Select Menu > System > User Maintain, and input the password;
2. Select Parameters Maintain > CO<sub>2</sub> and switch off Zero Recovery.

NOTE: CO<sub>2</sub> values displayed within 30 s after the zero calibration is started should be interpreted cautiously.

### 18.3.3 Sidestream CO<sub>2</sub> Module

#### 18.3.3.1 Measurement Steps

1. Fix the water trap to the water trap holder on the left side of the monitor, confirm it is well fixed.
2. Connect the sampling cannula or the sampling line to the water trap.
3. Set Work Mode to Measure.
4. For intubated patients, an airway adapter is required. For non-intubated patients,

place the nasal cannula or the sampling mask onto the patient.

### 18.3.3.2 Removing Exhaust Gases from the System

#### **WARNING**

Do not connect the exhaust tube to the ventilator circuit, connect the outlet to a scavenging system, cross infection can occur if sampling gas is returned to the breathing system. When using the sidestream CO<sub>2</sub> measurement on patients who are receiving or have recently received anesthetics, please avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

### 18.4 Setting the Gas Compensation

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O<sub>2</sub>, N<sub>2</sub>O and Helium in the mixture all influence CO<sub>2</sub> absorption. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

The following items are available in the Compensation Setting menu: N<sub>2</sub>O Compens., O<sub>2</sub> Compens., Anest. Agent, Vapor Compens. and Pump Rate. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O<sub>2</sub> and N<sub>2</sub>O, make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O<sub>2</sub>, and its volume is 60%, then O<sub>2</sub> compensation is: 100%\*60%=60%. AG concentration is decided by anaesthesia apparatus. After settings, confirm the changes to make the settings effective.

NOTE: Make sure compensation value is correctly set, otherwise the measurement accuracy may be affected.

### 18.5 Setting No Breath Detected Alarm Time

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1. Select the CO<sub>2</sub> tab > No Breath Detected;
2. Choose the No Breath Detected alarm time from the pop-up list.

**WARNING**

Safety and effectiveness of the respiration measurement method in the detection of No Breath Detected, particularly the apnea of prematurity and apnea of infancy, has not been established.

## 18.6 CO<sub>2</sub> Setup

Select the CO<sub>2</sub> parameter area or waveform area to enter the CO<sub>2</sub> Setup menu.

- Choose Mode and set it to Curve or Filled from the pop-up list;
- Choose Speed and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.
- Choose Scale and select the appropriate setting from the pop-up list.

## Chapter 19 Freeze

When monitoring a patient, the user may freeze the waveforms so that you can have a close examination of the patient's status. Generally, the user can review a frozen waveform of a maximum of 120 seconds. The freeze function of this monitor has the following features:

- Freeze status can be activated on any operating screen.
- Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed and recorded.

### 19.1 Entering/Exiting Freeze Status



Select the shortcut key to access the freeze status and the popup Freeze menu is displayed. In Freeze status, all waveforms are frozen and will no longer be refreshed. Click to exit the freeze status.

After exiting Freeze status, the system will clear screen waveforms and resume displaying real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.



NOTE: Select the shortcut key repeatedly over a short period of time may result in discontinuous waveforms on the screen.

### 19.2 Setting Freeze Duration

By setting the freeze duration, the monitor can exit freeze status automatically after certain period. To set the freeze duration:

1. On the Freeze menu, select Duration.
2. Select the desired setting from the pop-up list. Permanent/1/2/3/4/5/10/15/20/30/60 min are optional. When Permanent is selected, exit freeze status manually based on the actual situation.

### 19.3 Reviewing Frozen Waveform

By moving the frozen waveform, you may review a waveform of 120 seconds before it is frozen. For a waveform of less than 120 seconds, the remaining part is displayed as a straight line. Select Time on the Freeze menu and use the left/right arrow keys to move the frozen waves so that you can review the other parts of the frozen waves not displayed on the current screen.

# Chapter 20 Review

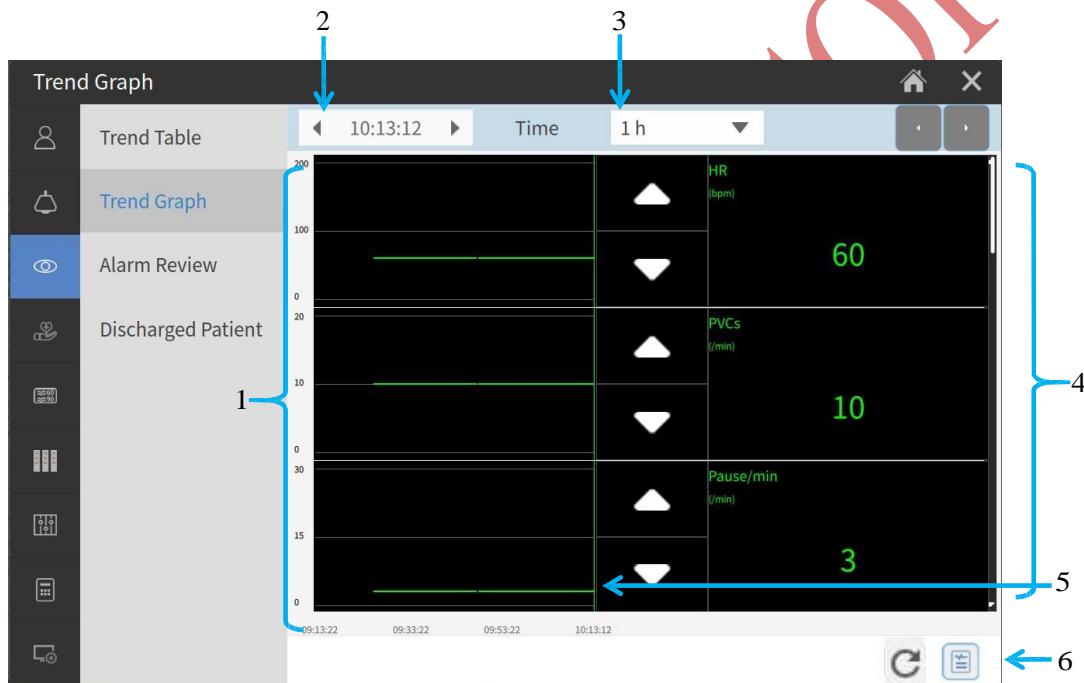
Users can view the trend data and alarm events through the review interface to understand the development and changes of the patient's condition.

Select the shortcut key  on the main screen to enter the review interface.

## 20.1 Trend Graph Review

To review the trend graph, select Menu > Review > Trend Graph.

In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time. With the exception of NIBP, other trends are displayed as continuous curves.



- 1 Trend curve area
- 2 Cursor time
- 3 Time
- 4 Trend data: displays measurement values at the cursor indicated time.
- 5 Cursor
- 6 Functional keys

In the trend graph review window:

- Select  and you can choose the required parameters to be displayed in the trend graph.
- Click  or  to adjust the trend scale.
- Select Time to change the length of trend data displayed on the current screen. 6 min, 12 min, 30 min, 1 h, 2 h, 4 h, 6 h, 12 h, 24 h, 36 h and 48 h are optional.

- Click different locations to adjust the cursor.
- Click or to browse more trends.
- Select to refresh and obtain the latest data.
- Select to print out the currently displayed trends through the recorder.

## 20.2 Trend Table Review

To review the trend table, select Menu > Review > Trend Table.

In the trend table review window:

- Select and you can choose the required parameters to be displayed in the trend table. The parameter selection in the trend table is synchronized with that in the trend graph.
- Select Interval to change the interval of the trend data. 1 s, 5 s, 30 s, 1 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min, NIBP and C.O. are optional. Select NIBP or C.O. to view the trend data according to the NIBP or C.O. measurement time.
- Click or to view more trends.
- Select to refresh and obtain the latest data.
- Select to print out the currently displayed trends through the recorder.
- Select Data Export to pop up the trend table data exporting interface after the user authentication.
  - ◆ Set start and end time of trend table review. Click to refresh the start time to the monitoring start time of the current patient and end time to the current system time.
  - ◆ Set Interval to change the resolution of the export data.
  - ◆ Select the USB flash drive on which you want to store the data. If “USB Drive Read Only” is prompted, repair the storage device or replace it with a new one.
  - ◆ Click Export to export the trend table data of the current patient. The trend table data is available in CSV format only.

## 20.3 Alarm Review

The monitor stores events in real time, including physiological alarm events and Arrhythmia events. When an event occurs, all the measurement numerics and the event-related waveforms 4/8/16 seconds before and after the event are stored.

To review the alarm event, select Menu > Review > Alarm Review.

In the alarm review window:

- View the alarm events: \*\*\* indicates high-level alarm, \*\* for medium-level alarm and \* for low-level alarm.
- Set Sort to filter events by alarm level or time.
- View the parameter values and alarm thresholds.
- Click a specific event to view waveform and parameter values at the event time. Select Back to return back to the alarm review list. Select Alarm Wave to set the time length to be displayed in the current window.
- Swipe the screen to browse more alarm events.
- Select  to access Alarm Review Setup menu:
  - ♦ Select Alarm Type to choose the required parameter to be reviewed.

NOTE:

- 1 When the alarm system is powered down, the log is maintained. The time of powering down will not be recorded in the system log.
- 2 A total loss of power has no impact on the stored log.
- 3 As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

## 20.4 Discharged Patients Review

Select Menu > Review > Discharged Patient to review the selected patient data.

In the Discharged Patient window:

- Select a specific patient from the list. Check the detailed data by selecting Trend Graph, Trend Table, Alarm Review, or Full Disclosure.
- Click Effective Date to sort the patients by time.
- Click  to delete the selected discharged patient data.

## 20.5 Full Disclosure Review

Up to 48 hours of waveform data can be reviewed in the Full Disclosure review window. To save the desired waveforms, select Menu > System > User Maintain > Storage, enable Waveform Storage and set the desired waveforms to be stored in the monitor.

Select Menu > Review > Full Disclosure to review the selected waveforms. Both the waveforms and numeric values can be viewed. In case of alarms, the background of the specific position on the time scale is highlighted with a colored block (highest priority alarm color).

In the Full Disclosure window:

- Select  to access the setup menu:
  - ◆ Select the waveforms (Maximum: 3) to be displayed.
  - ◆ Select the appropriate Speed for the waveforms.
- View the time scale at the top of window. The time scale indicates the entire time length. Drag the slider  left or right to locate the waveform data at a specific time and also to refresh the data in current screen accordingly.
  - ◆ Directly click the time scale to locate the slider .
  - ◆ Select the slider by the rotary knob and move it left or right by 10 minutes.
  - ◆ Select  or  to move the slider left or right by 10 minutes.
  - ◆ Select  or  to move the slider left or right by 90 minutes.
- View the current screen time scale at the bottom of the window. The current screen time scale indicates the time length of the current screen.
  - ◆ Select  or  to move the cursor time by second.
  - ◆ Select  or  to move the cursor time by page.
- Select  to access the expanded window:
  - ◆ Select Cursor View to display numeric values and alarms at the cursor indicated time. Click a specific alarm event select Detail to view waveforms and parameter values at the event time. Select Back to return back to the alarm review list. Select Alarm Wave to set the time duration to be displayed in the current window.
  - ◆ Select Alarm List to display the parameter alarms within the current screen time period. Click Locate to display the waveforms at the alarm time. Detail to view the alarm event details.
- Select  to refresh and obtain the latest data.
- Select  to pop up the data exporting interface after the user authentication.
  - ◆ Set start and end time. Click  to refresh the start time to the monitoring start time of the current patient and end time to the current system time.
  - ◆ Select the USB flash disk on which you want to store the data.
  - ◆ Click Export to export the selected data. The data is available in CSV format only.

# Chapter 21 Calculation

The monitor provides calculation function and titration table. Calculations are patient data that are not directly measured but calculated by the monitor.

Select Menu > Calculation to enter the calculation interface. The monitor can perform drug calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation and renal function calculation.

NOTE: The calculation function is independent of other monitoring functions and can therefore be used for patients being monitored by other monitors. Any operation in a calculation dialog does not affect the patient monitored by the current monitor.

## PRECAUTION

The calculation results are for reference only and the calculation significance must be determined by the physician.

## WARNING

The correctness of the input parameters and the suitability of the calculated results should be carefully verified. The manufacturer is not liable for any consequences arising from input or operation errors.

## 21.1 Drug Calculation

### 21.1.1 Calculation Procedures

1. Select Menu > Calculation > Drug Dose.
2. Select the right pull-down box of the Drug option and select the required drug name among the 15 drugs which are listed as follows. And the drug name of Drug A, Drug B, Drug C, Drug D and Drug E can be defined by the user. Select the unit of the total amount and dose according to the selected drug.
  - Drug A, Drug B, Drug C, Drug D and Drug E
  - Aminophylline
  - Dobutamine
  - Dopamine
  - Epinephrine

- Heparin
- Isuprel
- Lidocaine
- Nipride
- Nitroglycerin
- Pitocin

3. The system generates values that cannot be treated the calculation results. The user must enter the correct parameter value based on the doctor's instruction.
4. Manually enter the value of patient weight or directly obtain the value from the monitor by selecting Reset.
5. Enter the correct parameter value.
6. Confirm whether the calculation result is correct.

The following formulas are applied to dose calculation:

$$\text{Concentration} = \text{Amount} / \text{Volume}$$

$$\text{Inf. Rate} = \text{Dose} / \text{Concentration}$$

$$\text{Duration} = \text{Amount} / \text{Dose}$$

$$\text{Dose} = \text{Inf. Rate} \times \text{Concentration}$$

$$\text{Dose (weight based)} = \text{Inf. Rate} \times \text{Concentration} / \text{Weight}$$

$$\text{Drip Rate (GTT/min)} = \text{Inf. Rate (ml/hr)} / 60 \times \text{Drop Factor (GTT/ml)}$$

### 21.1.2 Calculation Unit

Each drug has the fixed unit or unit series to calculate. Among the same unit series, the unit binary varies with the entered parameter value.

The calculation units of the drugs are listed as follows:

| Drug   | Unit     |
|--|----------|
| Drug A, Drug B, Drug C, Aminophylline, Dobutamine, Dopamine, Epinephrine, Isuprel, Lidocaine, Nipride, Nitroglycerin | mg, mcg  |
| Drug D, Pitocin, Heparin   | KU, Unit |
| Drug E   | meq      |

When defining a drug, select Drug A, Drug B, Drug C, Drug D, and Drug E based on the unit series.

NOTE: Drip Rate and Drop Factor are unavailable in the neonatal mode.

### 21.1.3 Titration Table

After completing the drug calculation, the user can open the Titration on the Drug Dose interface.

The user can change the following items in the titration table:

- Basic
- Step

The data in the titration table will vary with the changes above. And the user can swipe the screen to observe more data.

## 21.2 Hemodynamic Calculation

### 21.2.1 Calculation Procedure

1. Select Menu > Calculation > Hemodynamics.
2. Manually enter the values required on this interface. You can also directly obtain the values of HR, patient height and patient weight, if they are available from the monitor by selecting Reset.
3. Select Calculate to output parameter value.

### 21.2.2 Input Parameters

| Items  | Unit  | English Full Name/Description   |
|--------|-------|---------------------------------|
| PAWP   | mmHg  | Pulmonary artery wedge pressure |
| CVP    | mmHg  | Central venous pressure         |
| C.O.   | L/min | Cardiac output                  |
| HR     | bpm   | Heart rate                      |
| EDV    | ml    | End-diastolic volume            |
| AP MAP | mmHg  | Mean Artery Pressure            |
| PA MAP | mmHg  | Pulmonary artery mean pressure  |
| Height | cm    | /                               |
| Weight | kg    | /                               |

### 21.2.3 Output Parameters

| Items | Unit                 | English Full Name/Description | Formula  |
|-------|----------------------|-------------------------------|--|
| CI    | L/min/m <sup>2</sup> | Cardiac index                 | CI (L/min/m <sup>2</sup> ) = C.O. (L/min)/BSA (m <sup>2</sup> )                                |
| BSA   | m <sup>2</sup>       | Body surface area             | BSA (m <sup>2</sup> ) = Weight <sup>0.425</sup> (kg) × Height <sup>0.725</sup> (cm) × 0.007184 |
| SV    | ml                   | Stroke volume                 | SV (ml) = C.O. (L/min)/HR (bpm) × 1000   |

|       |                                    |                                     |  |
|-------|------------------------------------|-------------------------------------|--|
| SVI   | ml/m <sup>2</sup>                  | Stroke volume index                 | $SVI \text{ (ml/m}^2\text{)} = SV \text{ (ml)}/BSA \text{ (m}^2\text{)}$                                       |
| SVR   | DS/cm <sup>5</sup>                 | Systemic vascular resistance        | $SVR \text{ (DS/cm}^5\text{)} = 80 \times [AP \text{ MAP (mmHg)} - CVP \text{ (mmHg)}]/C.O. \text{ (L/min)}$   |
| SVRI  | DS·m <sup>2</sup> /cm <sup>5</sup> | Systemic vascular resistance index  | $SVRI \text{ (DS·m}^2\text{/cm}^5\text{)} = SVR \text{ (DS/cm}^5\text{)} \times BSA \text{ (m}^2\text{)}$      |
| PVR   | DS/cm <sup>5</sup>                 | Pulmonary vascular resistance       | $PVR \text{ (DS/cm}^5\text{)} = 80 \times [PA \text{ MAP (mmHg)} - PAWP \text{ (mmHg)}]/C.O. \text{ (L/min)}$  |
| PVRI  | DS·m <sup>2</sup> /cm <sup>5</sup> | Pulmonary vascular resistance index | $PVRI \text{ (DS·m}^2\text{/cm}^5\text{)} = PVR \text{ (DS/cm}^5\text{)} \times BSA \text{ (m}^2\text{)}$      |
| LCW   | kg·m                               | Left cardiac work                   | $LCW \text{ (kg·m)} = 0.0136 \times [AP \text{ MAP (mmHg)} - PAWP \text{ (mmHg)}] \times C.O. \text{ (L/min)}$ |
| LCWI  | kg·m/m <sup>2</sup>                | Left cardiac work index             | $LCWI \text{ (kg·m/m}^2\text{)} = LCW \text{ (kg·m)}/BSA \text{ (m}^2\text{)}$                                 |
| RCW   | kg·m                               | Right cardiac work                  | $RCW \text{ (kg·m)} = 0.0136 \times [PA \text{ MAP (mmHg)} - CVP \text{ (mmHg)}] \times C.O. \text{ (L/min)}$  |
| RCWI  | kg·m/m <sup>2</sup>                | Right cardiac work index            | $RCWI \text{ (kg·m/m}^2\text{)} = RCW \text{ (kg·m)}/BSA \text{ (m}^2\text{)}$                                 |
| LVSW  | g·m                                | Left ventricular stroke work        | $LVSW \text{ (g·m)} = 0.0136 \times [AP \text{ MAP (mmHg)} - PAWP \text{ (mmHg)}] \times SV \text{ (ml)}$      |
| LWSWI | g·m/m <sup>2</sup>                 | Left ventricular stroke work index  | $LWSWI \text{ (g·m/m}^2\text{)} = LVSW \text{ (g·m)}/BSA \text{ (m}^2\text{)}$                                 |
| RVSW  | g·m                                | Right ventricular stroke work       | $RVSW \text{ (g·m)} = 0.0136 \times [PA \text{ MAP (mmHg)} - CVP \text{ (mmHg)}] \times SV \text{ (ml)}$       |
| RWSWI | g·m/m <sup>2</sup>                 | Right ventricular stroke work index | $RWSWI \text{ (g·m/m}^2\text{)} = RVSW \text{ (g·m)}/BSA \text{ (m}^2\text{)}$                                 |
| EF    | %                                  | Ejection fraction                   | $EF \text{ (\%)} = SV \text{ (ml)}/EDV \text{ (ml)} \times 100$  |

## 21.3 Oxygenation Calculation

### 21.3.1 Calculation Procedure

1. Select Menu > Calculation > Oxygenation.
2. Manually enter the values required on this interface. You can also directly obtain the values of patient height and patient weight if they are available from the monitor by selecting Reset.
3. Select Calculate to output parameter value.

### 21.3.2 Input Parameters

| Items             | Unit  | English Full Name/Description                      |
|-------------------|-------|--|
| FiO <sub>2</sub>  | %     | Percentage fraction of inspired oxygen             |
| PaO <sub>2</sub>  | mmHg  | Partial pressure of oxygen in the arteries         |
| PaCO <sub>2</sub> | mmHg  | Partial pressure of carbon dioxide in the arteries |
| SaO <sub>2</sub>  | %     | Arterial oxygen saturation                         |
| PvO <sub>2</sub>  | mmHg  | Partial pressure of oxygen in venous blood         |
| SvO <sub>2</sub>  | %     | Venous oxygen saturation                           |
| Hb                | g/L   | Hemoglobin   |
| RQ                | /     | Respiratory quotient                               |
| ATMP              | mmHg  | Atmospheric pressure                               |
| C.O.              | L/min | Cardiac output                                     |
| Height            | cm    | /  |
| Weight            | kg    | /  |

### 21.3.3 Output Parameters

| Items              | Unit           | English Full Name/Description           | Formula  |
|--------------------|----------------|---|--|
| BSA                | m <sup>2</sup> | Body surface area                       | $BSA (m^2) = \text{Weight}^{0.425} (\text{kg}) \times \text{Height}^{0.725} (\text{cm}) \times 0.007184$ |
| VO <sub>2</sub>    | ml/min         | Oxygen consumption                      | $VO_2 (\text{ml/min}) = \text{Ca}-\text{vO}_2 (\text{ml/L}) \times \text{C.O.} (\text{L/min})$           |
| Ca-vO <sub>2</sub> | ml/L           | Arteriovenous oxygen content difference | $\text{Ca}-\text{vO}_2 (\text{ml/L}) = \text{CaO}_2 (\text{ml/L}) - \text{CvO}_2 (\text{ml/L})$          |
| O <sub>2</sub> ER  | %              | Oxygen extraction ratio                 | $O_2\text{ER} (\%) = VO_2 (\text{ml/min})/DO_2 (\text{ml/min}) \times 100$                               |
| DO <sub>2</sub>    | ml/min         | Oxygen transport                        | $DO_2 (\text{ml/min}) = \text{CaO}_2 (\text{ml/L}) \times \text{C.O.} (\text{L/min})$                    |

|                                     |                       |   |   |
|-------------------------------------|-----------------------|---|---|
| PAO <sub>2</sub>                    | mmHg                  | Partial pressure of oxygen in the alveoli | $\text{PAO}_2 \text{ (mmHg)} = [\text{ATMP (mmHg)} - 47 \text{ mmHg}] \times \text{FiO}_2 \text{ (\%)} / 100 - \text{PaCO}_2 \text{ (mmHg)} \times [\text{FiO}_2 \text{ (\%)} / 100 + (1 - \text{FiO}_2 \text{ (\%)} / 100) / \text{RQ}]$ |
| AaDO <sub>2</sub>                   | mmHg                  | Alveolar-arterial oxygen difference       | $\text{AaDO}_2 \text{ (mmHg)} = \text{PAO}_2 \text{ (mmHg)} - \text{PaO}_2 \text{ (mmHg)}$  |
| CcO <sub>2</sub>                    | ml/L                  | Capillary oxygen content                  | $\text{CcO}_2 \text{ (ml/L)} = \text{Hb (g/L)} \times 1.34 + 0.031 \times \text{PAO}_2 \text{ (mmHg)}$  |
| Qs/Qt                               | %                     | Venous admixture                          | $\text{Qs/Qt (\%)} = [\text{CcO}_2 \text{ (ml/L)} - \text{CaO}_2 \text{ (ml/L)}] / [\text{CcO}_2 \text{ (ml/L)} - \text{CvO}_2 \text{ (ml/L)}] \times 100$  |
| AaDO <sub>2</sub> /PaO <sub>2</sub> | /                     | AaDO <sub>2</sub> /PaO <sub>2</sub>       | $\text{AaDO}_2 / \text{PaO}_2 = [\text{PAO}_2 \text{ (mmHg)} - \text{PaO}_2 \text{ (mmHg)}] / \text{PaO}_2 \text{ (mmHg)}$  |
| DO2I                                | ml/min/m <sup>2</sup> | Oxygen delivery index                     | $\text{DO2I (ml/min/m}^2\text{)} = \text{DO2 (ml/min)} / \text{BSA (m}^2\text{)}$   |
| VO2I                                | ml/min/m <sup>2</sup> | Oxygen consumption index                  | $\text{VO2I (ml/min/m}^2\text{)} = \text{VO2 (ml/min)} / \text{BSA (m}^2\text{)}$   |
| CaO <sub>2</sub>                    | ml/L                  | Arterial oxygen content                   | $\text{CaO}_2 \text{ (ml/L)} = 100 \times 1.34 \times \text{Hb (g/L)} \times \text{SaO}_2 \text{ (\%)} / 100 + 0.031 \times \text{PaO}_2 \text{ (mmHg)}$  |
| CvO <sub>2</sub>                    | ml/L                  | Venous oxygen content                     | $\text{CvO}_2 \text{ (ml/L)} = 100 \times 1.34 \times \text{Hb (g/L)} \times \text{SvO}_2 \text{ (\%)} / 100 + 0.031 \times \text{PvO}_2 \text{ (mmHg)}$  |

## 21.4 Ventilation Calculation

### 21.4.1 Calculation Procedure

1. Select Menu > Calculation > Ventilation.
2. Manually enter the values required on this interface. You can also directly obtain the available values from the monitor by selecting Reset.
3. Select Calculate to output parameter value.

### 21.4.2 Input Parameters

| Items             | Unit | English Full Name/Description                        |
|-------------------|------|--|
| FiO <sub>2</sub>  | %    | Percentage fraction of inspired oxygen               |
| RR                | rpm  | Respiration rate                                     |
| VT                | ml   | Tidal volume   |
| PaCO <sub>2</sub> | mmHg | Partial pressure of carbon dioxide in the arteries   |
| PaO <sub>2</sub>  | mmHg | Partial pressure of oxygen in the arteries           |
| RQ                | /    | Respiratory quotient                                 |
| PeCO <sub>2</sub> | mmHg | Partial pressure of mixed expiratory CO <sub>2</sub> |
| ATMP              | mmHg | Atmospheric pressure                                 |

### 21.4.3 Output Parameters

| Items                               | Unit  | English Full Name/Description                       | Formula   |
|-------------------------------------|-------|---|---|
| PAO <sub>2</sub>                    | mmHg  | Partial pressure of oxygen in the alveoli           | $\text{PAO}_2 \text{ (mmHg)} = [\text{ATMP (mmHg)} - 47 \text{ mmHg}] \times \text{FiO}_2 (\%) / 100 - \text{PaCO}_2 \text{ (mmHg)} \times [\text{FiO}_2 (\%) / 100 + (1 - \text{FiO}_2 (\%) / 100) / \text{RQ}]$ |
| AaDO <sub>2</sub>                   | mmHg  | Alveolar-arterial oxygen difference                 | $\text{AaDO}_2 \text{ (mmHg)} = \text{PAO}_2 \text{ (mmHg)} - \text{PaO}_2 \text{ (mmHg)}$  |
| AaDO <sub>2</sub> /PaO <sub>2</sub> | /     | AaDO <sub>2</sub> /PaO <sub>2</sub>                 | $\text{AaDO}_2/\text{PaO}_2 = [\text{PAO}_2 \text{ (mmHg)} - \text{PaO}_2 \text{ (mmHg)}] / \text{PaO}_2 \text{ (mmHg)}$  |
| MV                                  | L/min | Minute volume                                       | $\text{MV (L/min)} = \text{VT (ml)} \times \text{RR (rpm)} / 1000$  |
| VD                                  | ml    | Volume of physiological dead space                  | $\text{VD (ml)} = [(\text{PaCO}_2 \text{ (mmHg)} - \text{PeCO}_2 \text{ (mmHg)}) \times \text{MV (L/min)}] / (\text{MV (L/min)} - \text{VA (L/min)})$   |
| VD/VT                               | %     | Physiological dead space in percent of tidal volume | $\text{VD/VT (\%)} = [\text{VD (ml)} / \text{VT (ml)}] \times 100$  |
| VA                                  | L/min | Alveolar volume                                     | $\text{VA (L/min)} = [\text{VT (ml)} - \text{VD (ml)}] \times \text{RR (rpm)} / 1000$   |

## 21.5 Renal Function Calculation

### 21.5.1 Calculation Procedure

1. Select Menu > Calculation > Renal Function.
2. Manually enter the values required on this interface.
3. Select Calculate to output parameter value.

### 21.5.2 Input Parameters

| Items | Unit                    | English Full Name/Description |
|-------|-------------------------|-------------------------------|
| URK   | mmol/L                  | Urine potassium               |
| URNa  | mmol/L                  | Urinary sodium                |
| Urine | ml/24h                  | Urine                         |
| Posm  | mOsm/kgH <sub>2</sub> O | Plasm osmolality              |
| Uosm  | mOsm/kgH <sub>2</sub> O | Urine osmolality              |
| SerNa | mmol/L                  | Serum sodium                  |
| SCr   | umol/L                  | Serum creatinine              |
| UCr   | umol/L                  | Urine creatinine              |
| BUN   | mmol/L                  | Blood urea nitrogen           |
| UUN   | mmol/L                  | Urine urea nitrogen           |

### 21.5.3 Output Parameters

| Items   | Unit     | English Full Name/Description        | Formula   |
|---------|----------|--------------------------------------|---|
| URNaEx  | mmol/24h | Urine sodium excretion               | URNaEx (mmol/24h) = URNa (mmol/L) × Urine (ml/24h)/1000                               |
| URKEx   | mmol/24h | Urine potassium excretion            | URKEx (mmol/24h) = URK (mmol/L)   |
| Na/K    | %        | Sodium potassium ratio               | Na/K (%) = URNa (mmol/L)/URK (mmol/L) × 100   |
| CNa     | ml/24h   | Clearance of sodium                  | CNa (ml/24h) = URNa (mmol/L) × Urine (ml/24h)/SerNa (mmol/L)                          |
| CCr     | ml/min   | Creatinine clearance rate            | CCr (ml/min) = UCr (μmol/L) × Urine   |
| CUUN    | ml/min   | Urine urea nitrogen clearance rate   | CUUN (ml/min) = UUN (mmol/L) × Urine (ml/24h)/[BUN (mmol/L) × 24 × 100]               |
| FENa    | %        | Fractional excretion of sodium       | FENa (%) = [URNa (mmol/L) × SCr (μmol/L)]/[UCr (μmol/L) × SerNa (mmol/L)] × 100       |
| FEUr    | %        | Fractional Excretion of Urine        | FEUr (%) = [SCr (μmol/L) × UUN (mmol/L)]/[UCr (μmol/L) × BUN (mmol/L)] × 100          |
| Cosm    | ml/min   | Osmolar clearance                    | Cosm (ml/min) = [Uosm (mOsm/kgH2O) × Urine (ml/24h)]/[Posm (mOsm/kgH2O) × 24]         |
| CH2O    | ml/24h   | Free water clearance                 | CH2O (ml/24h) = Urine (ml/24h) - Uosm (mOsm/kgH2O) × Urine (ml/24h)/Posm (mOsm/kgH2O) |
| U/P osm | /        | Urine to plasma osmolality ratio     | U/P osm = Uosm  |
| BUN/SCr | /        | Blood urea nitrogen creatinine ratio | BUN/SCr = [BUN (mmol/L)/SCr (μmol/L)]   |
| U/SCr   | /        | Urine-serum creatinine ratio         | U/SCr = UCr (μmol/L)/SCr (μmol/L)   |

## Chapter 22 Clinical Assistive Applications (CAA)

### 22.1 Early Warning Score

User can use early warning score system to get an early warning score based on measurement value or input value of each vital sign. Depending on the score calculated, appropriate recommendations are displayed.

Early warning score system includes MEWS (Modified Early Warning Score), NEWS (National Early Warning Score), NEWS2 (National Early Warning Score 2), and PEWS (Pediatric Early Warning Score). Click Menu > System > User Maintain > Other Setups > Score to select the desired score system. Only one score system can be selected and the default score system is MEWS.

MEWS, NEWS and NEWS2 are intended for adult patients only. PEWS is intended for pediatric patients only.

NOTE: The score results are for reference only and the score significance must be determined by the physician.

#### 22.1.1 Accessing/Exiting Score Interface

Access the score interface in any of the following ways:

- Click Score shortcut key 
- Select Menu > CAA > Score.

To exit the interface: Click  button on the top right of the interface.

#### 22.1.2 Performing Warning Score

To perform warning score, follow these steps:

Manual scoring: Select Reset to clear the previous score and re-obtain the data from the monitor. Manually input the other parameter values. Click Start to perform scoring.

For NEWS2, set the SpO<sub>2</sub> Scale in NEWS2 interface:

- ◆ Scale 1: for patients without hypercapnic respiratory failure.
- ◆ Scale 2: for patients with a prescribed oxygen saturation requirement of 88–92%, for instance, COPD (Chronic Obstructive Pulmonary Disease) patients.

NOTE: If any of above information is missing, the monitor will inform the user that the parameter input is incomplete, unable to score.

### 22.1.3 Warning Score Trend

Trend table provides the monitored patient's scores during a period of time; it includes score time, score parameters and score. Click Trend Table or Trend Graph button in Warning Score interface to review the trend. Earlier trends will be replaced by later ones if the storage capacity is reached.

## 22.2 Glasgow Coma Scale (GCS)

Select Menu > CAA > Score > GCS to enter the GCS score interface. GCS is used for coma patients with various causes and objectively reflects patient's level of consciousness. GCS scores include eye opening reaction, speech reaction and motor reaction. Three aspects of behavior are independently measured: eye opening, verbal response, and motor response. The addition of the three scores is the coma scale.

GCS is intended for adults and pediatric patients.

### PRECAUTION

GCS is for reference only. It must be used in conjunction with clinical signs and symptoms of the patient.

To perform GCS scoring, follow these steps:

1. Respectively select an appropriate item that represents the patient's status for eye opening, verbal response, and motor response.
2. Click Start to perform scoring. Click Reset to clear the previous score and time.  
Click Trend Table or Trend Graph button in Warning Score interface to review the trend.

### 22.3 24h NIBP Summary

24h NIBP summary provides NIBP statistics of the current patient over the time scale. It allows the user to know the patient's condition over the last 24 hours. Select the

shortcut key  on the main screen, or select Menu > CAA > NIBP Summary to enter the interface. Select  to refresh and obtain the latest data.

24h NIBP summary interface provides the following information:

- ◆ NIBP data throughout the whole day/daytime/nighttime (average SYS/DIA/MAP, maximum SYS/DIA/MAP, minimum SYS/DIA/MAP, and measurement time).
- ◆ The percentage of SYS and DIA within the normal range, below the normal

- range, and above the normal range throughout the whole day.
- ◆ The night time duration. The night time can be set according to 24 hours format or 12 hours format. The minimum period can be set to 30 minutes. The default start time of night time is 20:00 (PM) and the default end time of night time is 06:00 (AM).

## 22.4 24h ECG Summary

24h ECG summary provides ECG statistics of the current patient within the last 24 hours. Select the shortcut key  on the main screen, or select Menu > CAA > ECG Summary to enter the interface. Select  to refresh and obtain the latest data.

24h ECG summary interface provides the following information:

- HR statistics
- QT/QTc measurement statistics
- Maximum and minimum ST corresponding to each lead
- Arrhythmia event statistics

NOTE:

1. The 24h ECG Summary is intended for the current patient, not for discharged patients.
2. Patient data is saved, collected and displayed together in the 24h ECG Summary, which is not recalculated.

## Chapter 23 Recording

A thermal dot matrix recorder is used for the monitor and can support many recording types and output patient information, measurement data, review data waveform and so forth.



|   |   |
|---|---|
| 1 | Recording indicator. ON: the recorder works correctly   |
| 2 | Paper feeding key: press this key to start or stop feeding recording paper without outputting anything on the paper |
| 3 | Paper outlet  |
| 4 | Recorder door   |

NOTE: If the blank recording paper is insufficient after recording is stopped, the user can press the paper feeding key on the recorder to feed more paper.

### 23.1 Performance of the Recorder

- Waveform record is printed at the rate of 12.5 mm/s, 25 mm/s or 50 mm/s.
- 48 mm record width and 50 mm record paper width.
- It can record up to three waveforms.
- User-selectable real-time recording time and waveform.
- Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

NOTE: It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

## 23.2 Starting and Stopping Recording

The monitor provides several types of stripe recording. You can start recording following the procedure below:

| Recording Type   | Description/ Procedure   |
|--|--|
| Continual real-time recording                              | Select at least one Rec waveform in Report Setup (A maximum of three waveforms can be selected), select Continual in Recording Duration. Select shortcut key  to start the recording. Press the button again to stop recording.   |
| 8-second real-time recording/20-second real-time recording | Select at least one Rec waveform in Report Setup (A maximum of three waveforms can be selected), select 8 s or 20 s in Recording Duration, set Record Interval as needed, select shortcut key  to start the recording. Select shortcut key  again to stop recording or when recording duration ends, the monitor stops recording automatically. The runtime for each wave is 8 seconds or 20 seconds. The record Interval can be set as: Off, 10 min, 20 min, 30 min, 40 min, 50 min, 1 h, 2 h, 3 h, 4 h. The default recording time is 8 s. |
| Trend graph recording                                      | Select Menu > Review > Trend Graph, click  to start recording.  |
| Trend table recording                                      | Select Menu > Review > Trend Table, click  to start recording.  |
| C.O. measurement recording                                 | Select C.O. Option > C.O. Measure, click  to start recording.   |
| NIBP trigger recording                                     | The monitor triggers recording at the completion of NIBP measurement.  |
| ST VIEW recording  | In the ST VIEW window, click  to start recording.   |
| QT VIEW recording  | In the QT VIEW window, click  to start recording.   |

To manually stop recording, click  again in the related windows.

The recorder will stop recording in the following situations:

- The recording task is finished.
- No paper in the recorder.
- Malfunction stops the recorder from running properly.
- The monitor enters into standby mode.

NOTE: You can also select shortcut key  to manually start or stop recording.

### 23.3 Parameter Alarm Trigger Recording

Select Menu > Alarm > Alarm Setup and set Alarm Rec. Time.

When the physiological alarm occurs and the alarm recording function is turned on, the monitor automatically records the output. The output waveform is the waveform of N/2 seconds before and after the alarm time. N is the preset waveform length of alarm recording. 8 seconds, 16 seconds and 32 seconds are optional. The default setting is 8 seconds.

### 23.4 Recorder Operations and Status Messages

#### 23.4.1 Record Paper Requirement

Only standard thermosensitive record paper can be used: otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive print head may be damaged.

#### 23.4.2 Proper Operation

- When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force: otherwise the recorder may be damaged.
- Do not operate the recorder without record paper.

#### 23.4.3 Paper Out

When the Recorder Out Of Paper alarm is displayed, the recorder cannot start. Please insert record paper properly.

#### 23.4.4 Replacing Paper

1. Pull outwards the upper arc part of the recorder door to release the casing, shown in the following figure.



2. Insert a new roll of paper into the paper cassette, printing side facing upwards.
3. Ensure proper position and tidy margin.

4. Pull some paper out from the top of the roller, and close the recorder door.

NOTE: Be careful when inserting papers. Avoid damaging the thermo-sensitive print head. Unless when inserting papers or shooting troubles, do not leave the recorder door open.

#### 23.4.5 Removing Paper Jam

When the recorder functions or sounds improperly, you should open the recorder casing to check for a paper jam. Remove the paper jam in the following way:

1. Open the recorder door as shown above.
2. Cut the record paper from the feeding edge.
3. Reload the paper and close the recorder door.

NOTE: Do not touch the thermo-sensitive print head when performing continuous recording.

## Chapter 24 Other Functions

### 24.1 Nurse Call

The monitor provides a dedicated nurse call port to output nurse call signal when a user-defined alarm occurs. To establish communication between the nurse call system and the monitor, use the dedicated nurse call cable to connect the hospital's nurse call system to the monitor's nurse call port.

Alarms are sent to the nurse call system given the following conditions are met:

- The nurse call system is enabled.
- A user-defined alarm occurs.
- Alarms are not paused or reset.

The nurse call function can be set through the following steps:

1. Select Menu > System > User Maintain, input the password.
2. Select Other Setups and enable Nurse Call.
3. Select Signal Type:
  - ◆ Continuous: the nurse call signal lasts until the alarm ends, which means the duration of a nurse call signal is equal to that of the alarm condition.
  - ◆ Pulse: the nurse call signal is a pulse signal, and the duration of each pulse is user-defined. When multiple alarms occur simultaneously, only one pulse signal is produced. If an alarm occurs but the previous one is not cleared, a new pulse signal will also be produced. Set Pulse Width to 1 s, 2 s, or 3 s, as desired.
4. Select Contact Type to set the work mode of the nurse call relay.
5. Select Alarm Level to set the priority of alarms sent to the nurse call system.
6. Select Alarm Type to set the type of alarms sent to the nurse call system.

#### **WARNING**

Do not rely exclusively on the nurse call system for alarm notifications. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.

#### **NOTE:**

1. Ensure the nurse call function is operating properly before use.
2. If you need to connect the monitor to the nurse call system, a dedicated nurse call cable is required. For more information, contact the service personnel for assistance.

## 24.2 Analog Output and Defibrillator Synchronization

The monitor provides analog output signals to accessory equipment. If a defibrillator is connected to the monitor, a defibrillator synchronization pulse can also be provided.

To activate the Analog Output function:

1. Select Menu > System > User Maintain, and input the password;
2. Select Other Setups > Auxiliary Output;
3. Select Analog Output, Defibrillation or Off.

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# Chapter 25 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The battery recharges whenever the monitor is connected to the AC power source. During monitoring, if the AC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

## 25.1 Battery Safety Information

### **WARNING**

- 1 Before using the rechargeable lithium-ion battery (hereinafter called lithium battery), be sure to read the user manual and safety precautions thoroughly.
- 2 The lithium battery can only be used for this device.
- 3 The lithium battery can only be charged in this device.
- 4 Do not reverse the lithium battery polarity.
- 5 Do not connect the positive (+) and negative (-) terminals with metal objects such as lead wire, which can result in short circuits.
- 6 The cycle life of the lithium battery is 300 charge. The service life of the lithium battery may shorten if it is used inappropriately. It is recommended to replace the lithium battery after 300 charge-discharge cycles, or it may cause safety risks such as heat and liquid leakage, and risks such as failure or decline of performance.
- 7 Do not heat or throw the lithium battery into a fire.
- 8 Do not immerse, throw, or wet the lithium battery in water, beverages or other liquids.
- 9 Do not use or leave lithium battery at high temperature (charging > 45 °C, discharging > 60 °C, such as in direct sunlight or in a very hot car), otherwise it may cause overheat, fire, malfunction to the lithium battery, shorten the service life of the lithium battery, or damage the lithium battery.
- 10 Keep lithium batteries out of the reach of children.
- 11 Do not place the lithium battery near microwave equipment or other cooking devices. If the lithium battery is heated or subjected to strong electromagnetic radiation, liquid leakage, heat, smoke, fire, and so forth. may occur.

**WARNING**

- 12 Do not hit with a hammer, step on, throw or drop to cause strong shock.
- 13 Do not weld the lithium battery directly.
- 14 Do not use a lithium battery of other specifications.
- 15 Do not use a lithium battery with serious scratch or deformation.
- 16 Power off the device, remove and stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage, or it may cause safety accidents such as heat, smoke, and fire.
- 17 Do not touch a leaking lithium battery. If the liquid leaked from the lithium battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.
- 18 When the device is running on lithium battery power, do not replace the lithium battery during operation of the device.
- 19 High internal temperature may also cause the lithium battery unable to be charged. Keep the device at room temperature and move it away from heat sources or out of direct sunlight. The lithium battery will resume charging when the temperature is within range again.
- 20 Lithium batteries should be charged, used and stored in places far away from static electricity.
- 21 Lithium batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or lithium batteries, please contact your local Civic Office, or the shop where you purchased the product.

## 25.2 Battery Power Indicator

The indicator labeled Battery on the front panel of the monitor illuminates in green when the monitor is battery powered and illuminates in yellow when battery is being charged. The indicator is not illuminated when the monitor is not powered or when AC power is applied.

## 25.3 Battery Status on the Main Screen

Battery status symbols show the status of each battery detected and the combined battery power remaining.



Remaining battery power: 76%~100%.



Remaining battery power: 51%~75%



Remaining battery power: 26%~50%



Remaining battery power: 2%~25%



Batteries are almost depleted (0~2%) and need to recharge immediately.



Batteries are depleted



Batteries are in charging.



No battery is installed.



Battery malfunction

## 25.4 Charging the Battery

To charge the battery, please follow the procedure:

1. Load the battery into the device and connect the device to the main source power.  
The battery indicator illuminates in yellow when battery is being charged.
2. Charge the battery until it is full, the battery indicator is off, and the battery power indicator is filled.

NOTE: It is recommended to charge the battery when the device is switched off to help improve the charging efficiency and save charging time.

## 25.5 Maintaining the Battery

The performance of rechargeable batteries may deteriorate over time. It is recommended to check and maintain the batteries regularly every 3 months.

1. Disconnect the patient from the device and stop all measurement.
2. Switch off the device, connect it to main source power, install the battery and fully charge it.
3. Disconnect the device from main source power, switch on the device and let the device run until there is no battery power left and the device shuts off.
4. Reconnect the device to main source power and charge the battery until it is full for use or charge to 40%~60% for storage.

NOTE:

- 1 Do not use the device on a patient during the battery maintenance.
- 2 Do not interrupt the battery maintenance process.

## 25.6 Storing the Battery

Remove the lithium battery and store it at a cool and dry environment if the lithium battery or the device is not used for a long time. Charge the batteries to 40%-60% for storage. Check and maintain the batteries regularly every 3 months. For more information, please see Section MaintainingtheBattery.

NOTE:

- 1 When storing batteries, make sure that the battery terminals do not come into contact with metallic objects.
- 2 The service life of the battery will be shortened if it is stored at high temperature for a long time. Storing batteries in a cool place can slow down the aging process. The ideal storage temperature is 15 °C.

## 25.7 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. If you suspect that the battery may have failed, check the battery performance.

See Step 1~Step 3 in Section MaintainingtheBatteryand record the running time of the battery which reflects the battery performance directly. If the running time is obviously less than the specified time in the specification, the battery may have reached its service life or malfunctioned, please change the battery or contact the service personnel. If the running time meets the specification, then the battery can continue to be used normally.

## 25.8 Replacing the Battery

To install or replace the battery, please follow the procedure:



- 1 Use a screwdriver to loosen the screw and open the battery door.
- 2 Take out the battery to be replaced.

3. Insert the new battery into the battery port.
4. Secure the battery and close the battery door.

## 25.9 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

**WARNING**

Do not disassemble batteries, put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

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## Chapter 26 Care and Cleaning

Use only the substances approved by the manufacturer and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

The manufacturer has validated the cleaning and disinfection instructions included in this user manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed to ensure adequate cleaning and disinfection.

### 26.1 Safety Instructions

#### Reusable products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- ▶ Follow the infection prevention policies and reprocessing regulations of the health-care facility.
- ▶ Follow the national infection prevention policies and reprocessing regulations.
- ▶ Use validated procedures for reprocessing.
- ▶ Reprocess reusable products after every use.
- ▶ Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices. Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.
- ▶ Check the products for signs of wear and replace them if necessary.

#### Disposable products

Disposable products have been designed, tested, and manufactured exclusively for single use. Reuse, reprocessing, or sterilization can result in failure of the accessory, incorrect measurements, and injury to the patient.

- ▶ Do not reuse disposable products.
- ▶ Do not reprocess disposable products.
- ▶ Do not use any disinfectants.

### 26.2 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product

lifetime or cause safety hazards.

- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

#### PRECAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or service engineer of the manufacturer.

NOTE:

- 1 Automated cleaning/disinfection to the equipment and accessories are prohibited.
- 2 To avoid blocking and affecting NIBP measurement, the user should clean the battery compartment periodically by opening the door and dust the vent. Do not use wet cotton swab to clean the vent. If NIBP measurement is still affected after cleaning, contact the service personnel of the manufacturer.

### ~~Cleaning~~ 26.3 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. See the cleaning agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

### 26.3.1 Cleaning the Monitor

#### **WARNING**

Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Remove all residual foreign matters from the surface of the monitor using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Use a clean cotton swab dampened with the cleaning solution to wipe the surface apertures of the equipment until no visible contaminants remain.
4. Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the equipment until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Dry the monitor in a ventilated and cool place.
7. If the monitor is not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the monitor to ensure that there is no damage.

### 26.3.2 Cleaning the Reusable Accessories

#### 26.3.2.1 Cleaning the Cable

1. Remove cable from the monitor.
2. Remove all residual foreign matters from the surface of the cable using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the cable with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Leave the cable to air dry.

7. If the cable is not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the cable to ensure that there is no damage.

### 26.3.2.2 Cleaning the Blood Pressure Cuff

#### Cleaning the Cuff:

1. Remove NIBP Cuff from the monitor, and take out the air bladder.
2. Remove all residual foreign matters from the surface of cuff and air bladder using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. Clean the surface of the cuff and the air bladder thoroughly until no visible contaminants remain.
4. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Air dry the cuff thoroughly after cleaning.
7. If the cuff and the air bladder are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the cuff and the air bladder to ensure that there is no damage.

#### Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.
2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
3. Adjust the bladder until it is in position.

### 26.3.2.3 Cleaning the SpO<sub>2</sub> Sensor

1. Remove SpO<sub>2</sub> sensors from the monitor.
2. Remove all residual foreign matters from the surface of SpO<sub>2</sub> sensors, including cables, using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.

4. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
6. Wipe off residual moisture with a dry cloth.
7. Leave the sensor to air dry.
8. If the SpO<sub>2</sub> sensors, including cables, are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 7.
9. Inspect the SpO<sub>2</sub> sensors, including cables, to ensure that there is no damage.

#### 26.3.2.4 Cleaning the TEMP Sensor

1. Remove TEMP sensors from the monitor.
2. Remove all residual foreign matters from the surface of TEMP sensors using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the sensor with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Leave the sensor to air dry.
7. If the TEMP sensors are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the TEMP sensors to ensure that there is no damage.

#### 26.3.2.5 Cleaning the IBP/C.O. Patient Cable

1. Remove IBP/C.O cable from the monitor.
2. Remove all residual foreign matters from the surface of cables using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Wipe the cables with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
4. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
5. Wipe off residual moisture with a dry cloth.
6. Leave the cables to air dry.

7. If the cables are not visually clean after cleaning, please repeat the cleaning steps through step 3 to step 6.
8. Inspect the cables to ensure that there is no damage.

## 26.4 Disinfection

For devices or accessories that have been in contact mucosal surface, High-Level disinfection must occur, for all other accessories, low-level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected.

The validated disinfectants for disinfecting the monitor are:

- Ethanol (75%)
- Ethanol (70%)
- Isopropanol (70%)
- Hydrogen Peroxide solution 0.5-1% concentration
- PDI Sani-Cloth Bleach Germicidal Disposable Wipes. (Composition: 0.63% Sodium Hypochlorite.)
- PDI Super Sani-Cloth Germicidal Disposable Wipes. (Composition: 55% Isopropyl alcohol, 0.25% Akly dimethyl benzyl ammonium chlorides, 0.25% Akyl ethylbenzyl ammonium chloride.)
- Diversey Oxivir 1 Wipes. (Composition: 0.5% Hydrogen Peroxide)
- Diversey Oxivir Tb Wipes. (Composition: 0.5% Hydrogen Peroxide)
- Sodium Hypochlorite solution 6500 ppm (household bleach diluted ~1:10)
- Health Essence Disinfecting Effervescent Tablets. (Composition: active chlorine, trichloroisocyanuric acid 500~1000mg/L)
- Clinell Sporicidal Wipes. (Composition: peracetic acid)
- Dian Erkang II Wipes. (Composition: 1.8g/L~2.2g/L Quaternary Ammonium, 14%~17% Isopropyl Alcohol, 36%-44% Ethanol)
- Mikrozid Sensitive Wipes. (Composition: 100 g solution contains the following active substances: 0.26 g Alkyl Dimethylbenzyl Ammonium Chloride, 0.26 g Didecyldimethylammonium Chloride, 0.26 g Alkyl Ethylbenzylammonium Chloride)
- Clorox Dispatch Hospital. (Composition: Sodium Hypochlorite 0.65%)
- Dismozon plus. (Composition: Magnesium Monoperoxyphthalate Hexahydrate 958 mg/g)
- Descosept AF wipes. (Composition: 100 g solution contains the following active substances: 42 g Ethanol and 0.05 g Didecyl Dimethyl Ammonium Chloride)

- Incidin Oxywipes. (Composition: Hydrogen Peroxide 1.5%)
- Terralin Liquid. (Composition: 100 g solution contains the following active substances: 42 g Ethanol and 35 g Propyl Alcohol)
- Mikrozid universal. (Composition: 100 g solution contains the following active substances: 17.4 g Propane and 12.6 g Ethanol)
- Dian Erkang Surface Wipes. (Composition: Didecyldimethylammonium Chloride, Dodecyl Dimethyl Benzyl Ammonium Chloride, Isopropyl Alcohol)
- Hydrogen Peroxide 3%.
- Clinell Universal Wipes. (Composition: RO pure water, surfactant, Double-Chain Quaternary Ammonium Salt Compound (w/w) 0.765%-0.935%)
- 0.5% sodium hypochlorite.
- 2% glutaraldehyde.
- 50% N-propanol.
- Clorox Bleach Gemicidal Wipes. (Composition: 0.55% Sodium Hypochlorite).
- Clorox disinfecting wipes. (Composition: 0.368% Chlorine Quaternary Ammonium Salt).
- Cleanisept wipes. (Composition: 100 g solution contains the following active substances: 0.5 g Alkyl Dimethylbenzyl Ammonium Chloride and 0.25 g Didecyldimethylammonium Chloride)
- Mikrozid AF wipes. (Composition: Ethanol, Isopropanol)
- Mikrozid PAA Wipes. (Composition: 100 g solution contains the following active substances: 0.06 g Peracetic Acid, Hydrogen Peroxide and Acetic Acid)
- Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes. (Composition: Hydrogen Peroxide 1.4%)

Final dilution shall be determined according to the chlorine concentration in the specific household bleach solution, bought from market.

The validated disinfectants for disinfecting the reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High-level disinfection of intracavitory temperature probe only)

Disinfecting agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. See the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

## PRECAUTION

- 1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
- 2 Although the monitor chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, unvalidated cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
- 3 Do not use phenol disinfectants because vinyl absorbs them. Do not use strong aromatic, chlorinated, ketone, ether or ester solvents. Do not immerse the cables for any prolonged period in alcohol, mild organic solvents, or highly alkaline solutions. Never boil or autoclave the cable. Vinyl withstands temperatures up to 100 °C but begins to soften at around 90 °C. Handle gently when hot and wipe away from the tip toward the cable.

## WARNING

The monitor and reusable accessories shall be disinfected to avoid patient cross contamination.

### 26.4.1 Disinfecting the Monitor

#### WARNING

Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Clean and dry the monitor according to the methods in section Cleaning the Monitor prior to disinfection.
3. Prepare the disinfectant solution.
4. Use a clean cotton swab dampened with the disinfectant solution to wipe the surface apertures of the equipment. Follow the disinfectant manufacturer's

- recommended contact time and mode.
5. Use a soft clean cloth dampened with the disinfectant solution to wipe the entire exterior surface of the equipment. Follow the disinfectant manufacturer's recommended contact time and mode.
  6. After disinfection, wipe off the disinfecting agent with a new sterile cloth dampened with sterile water.
  7. Dry the monitor for at least 30 minutes in a ventilated and cool place.
  8. Inspect the monitor to ensure that there is no damage.

#### 26.4.2 Disinfecting the Reusable Accessories

##### 26.4.2.1 Disinfecting the Cable

1. Remove the cable from the monitor.
2. Clean and dry the cable according to the methods in section CleaningtheCable prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the cable assembly to air dry for at least 30 minutes.
7. Inspect the cable to ensure that there is no damage.

##### 26.4.2.2 Disinfecting the Blood Pressure Cuff

###### Disinfecting the Cuff:

1. Remove NIBP Cuff from the monitor, and take out the air bladder.
2. Clean and dry the NIBP Cuff and air bladder according to the methods in section CleaningtheBloodPressureCuffprior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
5. Leave the cuff and air bladder to air dry for at least 30 minutes.
6. Inspect the cuff and the air bladder to ensure that there is no damage.

###### Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. See SectionCleaningtheBloodPressureCufffor more information.

**NOTE:** Prolonged use of disinfectant may cause discoloration of the cuff.

#### **26.4.2.3 Disinfecting the SpO<sub>2</sub> Sensor**

1. Remove SpO<sub>2</sub> sensors from the monitor.
2. Clean and dry the SpO<sub>2</sub> sensor according to the methods in section Cleaning the SpO<sub>2</sub> Sensor prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
5. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
6. Wipe off the disinfection solution with a dry cloth after disinfection.
7. Leave the sensor to air dry for at least 30 minutes.
8. Inspect the SpO<sub>2</sub> sensors, including cables, to ensure that there is no damage.

#### **26.4.2.4 Disinfecting the TEMP Sensor**

The intracavitory TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. See the instructions of the disinfectant for the methods of disinfection. High-level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Remove TEMP sensors from the monitor.
2. Clean and dry the TEMP Sensor according to the methods in section Cleaning the TEMP Sensor prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the sensor with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the sensor to air dry.
7. Inspect the TEMP sensors to ensure that there is no damage.

#### **26.4.2.5 Disinfecting the IBP/C.O. Patient Cable**

1. Remove IBP/C.O cable from the monitor.
2. Clean and dry the IBP/C.O. cables according to the methods in Section Cleaning the IBP/C.O. Patient Cable prior to disinfection.
3. Prepare the disinfectant solution.
4. Wipe the cables with a soft cloth dampened with the disinfectant solution.
5. Wipe off the disinfectant solution with a dry cloth after disinfection.
6. Leave the cables to air dry for at least 30 minutes.
7. Inspect the cables to ensure that there is no damage.

### **26.5 Cleaning and Disinfecting Other Accessories**

For cleaning and disinfecting other accessories, see the instructions delivered with the accessories. If the accessories are not accompanied by instructions, see this manual for the methods of cleaning and disinfecting the monitor.

### **26.6 After Reprocessing**

- After reprocessing, the equipment, cables, cuffs, sensors and other accessories should be checked to ensure there are no signs of aging, wear, cracks, deformation, discoloration or peeling, and so forth. Replacement should be taken or contact the service personal of the manufacturer if necessary.
- Assembling and attaching device-specific components

Prerequisite:

All components have been reprocessed and are dry.

- Preparation before next use of device

Assembling and fitting patient-specific accessories and consumables, i.e. SpO<sub>2</sub> sensors and NIBP Cuffs.

The device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.

### **26.7 Storage and Transport**

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

- Store dry and free of dust
- Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

# Chapter 27 Maintenance

## WARNING

- 1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- 2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.
- 3 The maintenance operations like software upgrade of the device can only be completed by qualified service professionals of the manufacturer.
- 4 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 27.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulation meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the recorder can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please do not use the monitor and contact local Customer Service Center.

## 27.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for qualified service professionals of the manufacturer only. Contact the qualified service provider of the manufacturer if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

| Maintenance and Test Schedule                            | Frequency   |
|--|---|
| Safety checks. Selected tests on the basis of IEC60601-1 | At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped. |
| Check all monitoring functions and measuring functions   | At least once every two years, or as needed.  |

The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by the manufacturer as repairable by service personnel.

## Chapter 28 Warranty and Service

### 28.1 Warranty

The manufacturer warrants that its products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by the manufacturer.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. The manufacturer will not provide a substitute product for use when the defective product is being repaired.

NOTE:



The products marked with this symbol apply to the European WEEE directive. This symbol indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.

### 28.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

## Chapter 29 Accessories

You can order accessories from supplies of the manufacturer or consult your local representative for details.

### WARNING

- 1 Never reuse disposable transducers, sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard.
- 2 Use only accessories approved by the manufacturer. Using accessories not approved by the manufacturer may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by the manufacturer with patient monitors by other manufacturers.
- 3 Sterilized accessories are already sterilized, see the package labeling for detailed method. Do not use a sterilized accessory if its packaging is damaged.

#### NOTE:

Transducers and sensors have a limited shelf life. See the package labeling.

The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1.

The following cables may not all be available in all countries. Please check availability with your local supplier of the manufacturer.

### 29.1 ECG Accessories

| Part Number  | Accessories                                |
|--------------|--|
| ECG Cable    |  |
| 01.57.471380 | 3-lead, 12-pin, Defib-proof, AHA, Snap     |
| 01.57.471388 | 3-lead, 12-pin, ESU-proof, AHA, Snap       |
| 01.57.471378 | 3-lead, 12-pin, Defib-proof, AHA, Clip     |
| 01.57.471386 | 3-lead, 12-pin, ESU-proof, AHA, Clip       |
| 01.57.471379 | 3-lead, 12-pin, Defib-proof, IEC, Snap     |
| 01.57.471387 | 3-lead, 12-pin, ESU-proof, IEC, Snap       |
| 01.57.471377 | 3-lead, 12-pin, Defib-proof, IEC, Clip     |
| 01.57.471385 | 3-lead, 12-pin, ESU-proof, IEC, Clip       |
| 01.57.471226 | 5-lead, 12-pin, ESU-proof, Adult/pediatric |

| Part Number  | Accessories  |
|--------------|--|
| 01.57.471227 | ECG trunk cable, 5-lead, 12-pin, ESU-proof, AHA/IEC, 5.0 m, reusable |
| 01.57.471228 | 5-lead, 12-pin, Defib-proof, Adult/pediatric                         |
| 01.57.471229 | 5-lead, 12-pin, Defib-proof, Adult/pediatric, Extended               |
| 01.13.036620 | 5-lead, Clip, AHA, Adult/pediatric, Extended                         |
| 01.13.036621 | 5-lead, Clip, AHA, Adult/pediatric                                   |
| 01.13.036622 | 5-lead, Snap, AHA, Adult/pediatric, Extended                         |
| 01.13.036623 | 5-lead, Snap, AHA, Adult/pediatric                                   |
| 01.13.036624 | 5-lead, Clip, IEC, Adult/pediatric, Extended                         |
| 01.13.036625 | 5-lead, Clip, IEC, Adult/pediatric                                   |
| 01.13.036626 | 5-lead, Snap, IEC, Adult/pediatric, Extended                         |
| 01.13.036627 | 5-lead, Snap, IEC, Adult/pediatric                                   |
| 01.57.471979 | 6-lead, 12-pin, Defib-proof, Adult/pediatric                         |
| 01.57.471980 | 6-lead, Clip, AHA, Adult/pediatric                                   |
| 01.57.471981 | 6-lead, Snap, AHA, Adult/pediatric                                   |
| 01.57.471982 | 6-lead, Clip, IEC, Adult/pediatric                                   |
| 01.57.471983 | 6-lead, Snap, IEC, Adult/pediatric                                   |
| 01.57.040203 | 12-lead, Snap, IEC, Adult/pediatric                                  |
| 01.57.471163 | 12-lead, Clip, IEC, Adult/pediatric                                  |
| 01.57.109101 | 12-lead, Snap, AHA, Adult/pediatric                                  |
| 01.57.471169 | 12-lead, Clip, AHA, Adult/pediatric                                  |
| 01.57.471072 | 12-lead, 12-pin, Defib-proof, AHA, Adult/pediatric                   |
| 01.57.471168 | 12-lead, 12-pin, Defib-proof, IEC, Adult/pediatric                   |
| 01.57.471461 | 3-lead, Clip, IEC, 1.0 m, Reusable                                   |
| 01.57.471462 | ECG limb wires, 3-lead, snap, IEC, 1.0 m, reusable                   |
| 01.57.471463 | 3-lead, Clip, AHA, 1.0 m, Reusable                                   |
| 01.57.471464 | ECG limb wires, 3-lead, snap, AHA, 1.0 m, reusable                   |
| 01.57.471465 | 5-lead, 12-pin, Defib-proof, Clip, IEC, 3.4 m, Reusable              |
| 01.57.471466 | 5-lead, 12-pin, Defib-proof, Clip, AHA, 3.4 m, Reusable              |
| 01.57.471467 | 5-lead, 12-pin, Defib-proof, Snap, IEC, 3.4 m, Reusable              |
| 01.57.471468 | 5-lead, 12-pin, Defib-proof, Snap, AHA, 3.4 m, Reusable              |
| 01.57.471473 | 5-lead, 12-pin, ESU-proof, Clip, IEC, 3.4 m, Reusable                |
| 01.57.471474 | 5-Lead, 12-pin, ESU-proof, Clip, AHA, 3.4 m, Reusable                |
| 01.57.471475 | 5-Lead, 12-pin, ESU-proof, Snap, IEC, 3.4 m, Reusable                |
| 01.57.471476 | 5-lead, 12-pin, ESU-proof, Snap, AHA, 3.4 m, Reusable                |
| 01.57.471481 | 3-lead, 12-pin, ESU-proof, AHA/IEC, 2.7 m, Reusable                  |
| 01.57.471482 | 3-lead, 12-pin, ESU-proof, AHA/IEC, 5.0 m, Reusable                  |
| 01.57.471483 | 3-lead, 12-pin, Defib-proof, AHA/IEC, 2.7 m, Reusable                |

| Part Number          | Accessories   |
|----------------------|---|
| 01.57.471484         | 3-lead, 12-pin, Defib-proof, AHA/IEC, 5.0 m, Reusable |
| 01.57.471196         | 3-lead, Snap, AHA, Neonate                            |
| 01.57.471198         | 3-lead, Clip, AHA, Neonate                            |
| 01.57.471195         | 3-lead, Snap, IEC, Neonate                            |
| 01.57.471197         | 3-lead, Clip, IEC, Neonate                            |
| 01.57.471194         | 3-lead, 12-pin, Defib-proof, Neonate                  |
| <b>ECG Electrode</b> |   |
| 01.57.471861         | Disposable ECG Electrodes                             |
| 01.57.471858         | Disposable ECG Electrodes                             |
| 01.57.471862         | Disposable ECG Electrodes                             |
| 01.57.471859         | Disposable ECG Electrodes                             |
| 01.57.471897         | Disposable ECG Electrodes                             |
| 01.57.471898         | Disposable ECG Electrodes                             |
| 01.57.472011         | Disposable ECG Electrodes                             |
| 01.57.472012         | Disposable ECG Electrodes                             |
| 01.57.472013         | Disposable ECG Electrodes                             |
| 01.57.472014         | Disposable ECG Electrodes                             |

## 29.2 SpO<sub>2</sub> Accessories

| Part Number                            | Accessories  |
|--|--|
| <b>SpO<sub>2</sub> Sensor</b>          |  |
| 02.57.225029                           | 7-pin SH1 Adult Reusable SpO <sub>2</sub> Sensor /adult, 2.5 m               |
| 02.01.210120                           | SH1 Adult Reusable SpO <sub>2</sub> Sensor (DB9)                             |
| 02.01.210673                           | SH3 Neonate Wrap SpO <sub>2</sub> Sensor                                     |
| 02.01.210122                           | SH4 Adult Silicone Soft-tip SpO <sub>2</sub> Sensor                          |
| 02.01.210121                           | SH5 pediatric Silicone Soft-tip SpO <sub>2</sub> Sensor                      |
| 02.57.225000                           | SpO <sub>2</sub> Sensor, Ear Clip, Adult/Pediatric, 1 m, reusable            |
| 01.57.471235                           | SHD-A SpO <sub>2</sub> Sensor, adult, disposable                             |
| 01.57.471236                           | SHD-P SpO <sub>2</sub> Sensor, pediatric, disposable                         |
| 01.57.471237                           | SHD-I SpO <sub>2</sub> Sensor, Infant, disposable                            |
| 01.57.471238                           | SHD-N SpO <sub>2</sub> Sensor, Neonate, disposable                           |
| <b>SpO<sub>2</sub> Extension Cable</b> |  |
| 01.57.471068                           | SpO <sub>2</sub> Extension cable, 2 m  |
| 01.57.471789                           | 7-pin SpO <sub>2</sub> adapter cable/SpO <sub>2</sub> Extension cable, 4.0 m |

## 29.3 NIBP Accessories

| Part Number  | Accessories                                    |
|--------------|--|
| NIBP Cuff    |  |
| 01.57.471326 | NIBP Cuff, E5, Infant,10-15cm, reusable        |
| 01.57.471327 | NIBP Cuff, E6, Small child,13-17cm, reusable   |
| 01.57.471328 | NIBP Cuff, E7, Child,16-21.5cm, reusable       |
| 01.57.471329 | NIBP Cuff, E8, Small adult,20.5-28cm, reusable |
| 01.57.471330 | NIBP Cuff, E9, Adult,27-35cm, reusable         |
| 01.57.471331 | NIBP Cuff, E10, Large adult,34-43cm, reusable  |
| 01.57.471323 | NIBP Cuff, Neonate, 10cm-15cm, reusable        |
| 01.57.471324 | NIBP Cuff, Neonate, 6cm-11cm, reusable         |
| 01.57.471157 | NIBP Cuff, neonatal #1, 3-6cm,disposable       |
| 01.57.471158 | NIBP Cuff, neonatal #2, 4-8cm,disposable       |
| 01.57.471159 | NIBP Cuff, neonatal #3, 6-11cm,disposable      |
| 01.57.471160 | NIBP Cuff, neonatal #4, 7-13cm,disposable      |
| 01.57.471161 | NIBP Cuff, neonatal #5, 8-15cm,disposable      |
| NIBP Tube    |  |
| 01.59.473007 | NIBP Hose/3.0 m,Φ7.2 mm*Φ3.6 mm, TPU 85A, gray |

## 29.4 TEMP Accessories

| Part Number       | Accessories   |
|-------------------|---|
| Temperature Probe |   |
| 01.15.040225      | Temperature Probe/Skin, adult, 3 m, reusable                  |
| 01.15.040226      | Temperature Probe/Skin, adult, 3 m, reusable                  |
| 01.15.040227      | Temperature Probe/rectal/oral, adult, 3 m, reusable           |
| 01.15.040228      | Temperature Probe, rectal/oral, adult, 3 m, reusable          |
| 01.15.040253      | Temperature Probe/Skin, neonatal/Infant, 3 m, reusable        |
| 01.15.040254      | Temperature Probe/rectal/oral, neonatal/Infant, 3 m, reusable |
| 01.15.040255      | Temperature Probe/Skin, neonatal/Infant, 3 m, reusable        |
| 01.15.040256      | Temperature Probe/rectal/oral, neonatal/Infant, 3 m, reusable |

## 29.5 IBP Accessories

| Part Number    | Accessories                             |
|----------------|---|
| IBP Transducer |   |
| 01.57.471664   | Disposable Pressure Transducer/PT161103 |
| 01.57.471665   | Disposable Pressure Transducer/PT151103 |
| 01.57.471666   | Disposable Pressure Transducer/PT141103 |

| Part Number  | Accessories   |
|--------------|---|
| 01.57.040121 | Disposable Pressure Transducer/DTXPlus DT-4812                        |
| IBP Cable    |   |
| 01.57.471971 | 12 pin, dual channel, IBP cable (BD)                                  |
| 01.57.471972 | 12 pin, dual channel, IBP cable (EDWARD)                              |
| 01.57.471973 | 12 pin, dual channel, IBP cable (ABBOTT)                              |
| 01.57.471974 | 12 pin, dual channel, IBP cable (UTAH)                                |
| 01.57.471975 | 12 pin, dual channel, IBP cable (B.Braun)                             |
| 01.57.471070 | IBP Pressure transducer interface cable/Interface model BD            |
| 01.57.471172 | IBP Pressure transducer interface cable/EDWARD type interface         |
| 01.57.471173 | IBP Pressure transducer interface cable/ABBOTT type interface         |
| 01.57.471166 | IBP Pressure transducer interface cable/the UTAH type interface       |
| 01.57.471836 | IBP Pressure transducer interface cable/12 pin,B.Braun type interface |

## 29.6 C.O. Accessories

| Part Number  | Accessories  |
|--------------|--|
| 01.57.471071 | Cardiac output cable   |
| 01.13.040119 | In-line Injection temperature probe (BD 684056-SP4042)         |
| 01.57.040120 | In-line Injection temperature probe housing (BD 680006-SP5045) |
| 01.57.040121 | IDTX Enhanced SPU Transducer/BD DT-4812                        |
| 01.57.100175 | Control Syringe (Medex MX387)                                  |
| 01.57.472712 | Connection cable   |

NOTE: The Thermodilution Catheter is required when measuring C.O.. Swan-Ganz catheter (Type 131HF7 and 741HF7), manufactured by Edwards Lifesciences Corporation, has been validated to be compatible with the monitor. See Edwards for more details.

## 29.7 CO<sub>2</sub> Accessories

| Part Number  | Accessories   |
|--------------|---|
| 02.01.210520 | Dewatering Cup(Single Patient Use, Adult/Pediatric 10 ml)                             |
| 01.57.471275 | CO <sub>2</sub> Sampling Line with Male Luer Lock, 2.0 m                              |
| 01.57.471282 | All Purpose Sampling Cannula without filter (Non Sterile). Size: Adult                |
| 01.57.471283 | All Purpose Sampling Cannula without filter (Non Sterile). Size: Infant               |
| 01.57.471284 | All Purpose Sampling Cannula without filter (Non Sterile). Size: Neonate              |
| 01.57.471285 | Duo Flow O <sub>2</sub> +CO <sub>2</sub> Sampling Cannula (Non Sterile). Size: Adult  |
| 01.57.471286 | Duo Flow O <sub>2</sub> +CO <sub>2</sub> Sampling Cannula (Non Sterile). Size: Child  |
| 01.57.471287 | Capnomask O <sub>2</sub> +CO <sub>2</sub> Sampling Cannula (Non Sterile). Size: Adult |
| 01.57.471288 | Capnomask O <sub>2</sub> +CO <sub>2</sub> Sampling Cannula (Non Sterile). Size: Child |

## 29.8 Other Accessories

| Part Number  | Accessories   |
|--------------|---|
| 01.13.036638 | Power cable, length 1.8 m, VDE                              |
| 01.13.037122 | Power cable, length 1.8 m, American standard, medical grade |
| 01.13.114214 | Potential Equalization Conductor                            |
| 01.21.064380 | Rechargeable Lithium-Ion Battery, 2550 mAh, 10.8 V          |
| 01.21.064381 | Rechargeable Lithium-Ion Battery, 5100 mAh, 10.8 V          |
| 01.57.078035 | Recorder paper  |
| 01.23.068023 | Linear Barcode Scanner                                      |
| 01.18.052245 | Netac USB flash disk (U208, 4G, USB2.0)                     |
| 02.01.210633 | Unicode recorder, Serial/parallel port                      |
| 02.01.039449 | CX/UX series quick release wall mounting assembly           |
| 83.60.263112 | MT-206 rolling stand  |
| 83.60.263113 | MT-206 (S) rolling stand                                    |
| 83.60.263114 | MT-300 rolling stand  |

NOTE: The part name may vary depending on context, but the part number is constant.

# A Product Specification

**NOTE:**

The performance of the equipment with  $\star$  mark is determined to be essential performance.

## A.1 Classification

|                                   |   |
|-----------------------------------|---|
| Anti-electroshock type            | Class I equipment and internal powered equipment                        |
| Anti-electroshock degree          | CF  |
| Ingress Protection                | IPX1  |
| Disinfection/sterilization method | See Chapter Care and Cleaning for details.                              |
| Working system                    | Continuous operation equipment  |
| Compliant with Standards          | IEC 60601-1; IEC 60601-1-2; EN 60601-1;<br>EN 60601-1-2; IEC 80601-2-49 |

## A.2 Physical Specifications

### A.2.1 Size and Weight

| Product  | Size ( $\pm 5$ mm)               | Weight*    |
|----------|----------------------------------|------------|
| PM PRO 4 | 330 mm (W)*244 mm (H)*178 mm (D) | $\pm 3$ kg |

\*Standard configuration with battery, excluding accessories.

### A.2.2 Environment Specification

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products. The unspecified module environment specifications are consistent with the main unit environment specifications.

|                          |                                   |
|--------------------------|-----------------------------------|
| Component                | Main unit                         |
| <b>Temperature</b>       |                                   |
| Working                  | 0 °C to 40 °C (32 °F to 104 °F)   |
| Transport and Storage    | -20 °C to 60 °C (-4 °F to 140 °F) |
| <b>Relative Humidity</b> |                                   |
| Working                  | 15%RH to 95%RH (non-condensing)   |
| Transport and Storage    | 10%RH to 95%RH (non-condensing)   |

| Barometric Pressure   |                     |
|-----------------------|---------------------|
| Working               | 57 kPa to 107.4 kPa |
| Transport and Storage | 16 kPa to 107.4 kPa |

### A.2.3 Power Supply Specifications

|                              |                |
|------------------------------|----------------|
| AC Voltage                   | 100 V to 240 V |
| Input Current                | 0.6 A to 0.3 A |
| Frequency                    | 50 Hz/60 Hz    |
| Over Current Fuse Protection | Support        |

### A.2.4 Battery Specification

|                        |  |                        |                               |
|------------------------|--|------------------------|-------------------------------|
| Operating Time         | PM PRO 4   | One battery (2550 mAh) | $\geq 4$ h                    |
| Condition              | At $25\pm 5$ °C, with (a) new fully charged battery/batteries, 3-lead ECG cable and SpO <sub>2</sub> sensor connected, NIBP module set at an interval of 15 minutes, and screen brightness set to “1”. |                        |                               |
| Charge Time            | PM PRO 4   | One battery (2550 mAh) | $\leq 3.5$ h (monitor is off) |
| Condition              | Environment temperature: 20 °C to 30 °C. $\geq 90\%$ charged.  |                        |                               |
| Charge/Discharge Cycle | 300 times  |                        |                               |

### A.2.5 Display

| Product  | Display   | Messages   |
|----------|---|--|
| PM PRO 4 | Display screen: 13-inch color TFT, supporting touch screen<br>Resolution: 1920×1080 | A maximum of 10 waveforms<br>One power LED<br>One AC power LED<br>One alarm LED<br>One battery LED |

### A.2.6 Recorder

|                             |                             |
|-----------------------------|-----------------------------|
| Record Width                | 48 mm                       |
| Record Paper Width          | 50 mm                       |
| Paper Speed                 | 12.5 mm/s, 25 mm/s, 50 mm/s |
| Number of waveform channels | A maximum of 3              |

### A.2.7 Data Storage

|                          |                                     |
|--------------------------|-------------------------------------|
| Trend Data               | 48 hours @ 1 s<br>240 hours @ 1 min |
| NIBP Measurement         | At least 1600 sets                  |
| Alarm Events             | Up to 1800 sets                     |
| Full Disclosure Waveform | 48 hours @ 1 s                      |

### A.3 Wi-Fi

|                 |  |
|-----------------|--|
| IEEE            | 802.11a/b/g/n  |
| Bandwidth       | 20 M/40 M  |
| Frequency Band  | 2.4 G/5 G  |
| Modulation Mode | 802.11a/g/n: OFDM<br>802.11b: CCK and DSSS                       |
| Antenna         | Single antenna, 2.4 GHz gain $\leq$ 3.0<br>5 GHz gain $\leq$ 3.5 |
| Power voltage   | 3.3 V  |
| Bluetooth       | Dual mode BLE4.0+EDR/BR  |
| Connector       | SDIO2.0 for Wi-Fi, UART for BT                                   |

### A.4 ECG

Complies with IEC 60601-2-25, IEC 60601-2-27.

|  |  |
|--|--|
| Lead Mode                                | 3 Electrodes: I, II, III<br>5 Electrodes: I, II, III, aVR, aVL, aVF, V<br>6 Electrodes: I, II, III, aVR, aVL, aVF, and leads corresponding to Va Vb.<br>10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 |
| Electrode Standard                       | AHA, IEC   |
| ☆Display Sensitivity<br>(Gain Selection) | 1.25 mm/mV ( $\times 0.125$ ), 2.5 mm/mV ( $\times 0.25$ ), 5 mm/mV ( $\times 0.5$ ), 10 mm/mV<br>( $\times 1$ ), 20 mm/mV ( $\times 2$ ), , 40 mm/mV ( $\times 4$ ), AUTO gain  |
| ☆Sweep                                   | 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s   |

|  |  |
|--|--|
| Bandwidth (-3dB)<br>(Output amplitude relative to that for a 5 Hz sinusoidal input signal) | Diagnosis: 0.05 Hz to 150 Hz<br>ST: 0.05 Hz to 40 Hz<br>Monitor and Monitor (Hi-Fi): 0.5 Hz to 40 Hz<br>Surgery: 1 Hz to 20 Hz<br>Enhanced: 2 Hz ~18 Hz<br>Customized: High-pass Filter and Low-pass Filter (See Changing the ECG Filter Settings) |
| ☆CMRR (Common Mode Rejection Ratio)  | Diagnosis: > 95 dB<br>ST: > 105 dB<br>Monitor and Monitor (Hi-Fi): > 105 dB<br>Surgery: > 105 dB<br>Enhanced: > 105 dB<br>Customized: > 105 dB (Low-pass Filter < 40 Hz)<br>> 95 dB (Low-pass Filter > 40 Hz)                                      |
| Hum Filter   | In diagnosis, ST, monitor, surgery, enhanced and customized modes:<br>50 Hz/60 Hz (Hum Filter can be turned on or off manually)  |
| ☆Differential Input Impedance  | > 5 MΩ   |
| ☆Input Signal Range  | ±10 mV PP  |
| ☆Accuracy of Signal Reproduction   | An error of $\leq \pm 20\%$ of the nominal value of the output or ±100 µV, whichever is greater.<br><br>The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.   |
| ☆Electrode Offset Potential Tolerance  | ±800 mV  |
| Auxiliary Current (Leads off detection)  | Active electrode: < 100 nA<br>Reference electrode: < 900 nA  |
| ☆Recovery Time After Defibrillation  | < 5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)   |
| Leakage Current of Patient   | < 10 µA  |
| Scale Signal   | 1 mV PP, accuracy is ±5%   |
| ☆System Noise  | < 30 µVPP  |
| ☆Multichannel Crosstalk  | ≤ 5% of the input signal<br><br>Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.  |

|   |     |  |
|---|-----|--|
| ☆Frequency<br>Impulse Response  | and | Frequency response:<br><br>Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71 % to 110 % at 0.67 Hz and 40 Hz.<br><br>Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm.<br><br>Impulse response:<br><br>Displacement value: $\leq 0.1$ mV<br><br>Slope: $\leq 0.3$ mV/s following the end of the pulse.<br><br>Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8. |
|   |     | Cut mode: 300 W<br><br>Coagulation mode: 100 W<br><br>Restore time: $\leq 10$ s  |
| Electrosurgical<br>Interference<br>Suppression  |     | Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.  |
| Sampling Frequency  |     | 1000 Hz  |
| Sampling Channel<br>Switch Time   |     | < 80 $\mu$ s   |
| A/D Precision   |     | 24 Bits (Minimum resolution: 0.077uV/LSB)  |
| ☆Baseline Reset Time  |     | < 3 s  |
| <b>Pace Pulse without overshoot</b>   |     |  |
| ☆Pulse Indicator  |     | Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met:<br><br>Amplitude: $\pm 2$ mV to $\pm 700$ mV<br><br>Width: 0.1 ms to 2.0 ms<br><br>Ascending time: 10 $\mu$ s to 100 $\mu$ s   |
| ☆Pulse Rejection  |     | Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met:<br><br>Amplitude: $\pm 2$ mV to $\pm 700$ mV<br><br>Width: 0.1 ms to 2.0 ms<br><br>Ascending time: 10 $\mu$ s to 100 $\mu$ s   |
| <b>Pace Pulse Detecting Lead:</b> one among I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 |     |  |
| <b>Heart Rate</b>   |     |  |
| <b>HR Calculation</b>   |     |  |
| ☆Range  |     | ADU: 15 bpm to 300 bpm<br><br>PED/NEO: 15 bpm to 350 bpm   |
| ☆Accuracy   |     | $\pm 1\%$ or 1 bpm, whichever is greater   |
| Resolution  |     | 1 bpm (For display and alarm limit)  |

|  |   |
|--|---|
| Sensitivity                                | $\geq 300 \mu\text{VPP}$  |
| ☆QRS Detection Range                       | <p>The detection range has exceeded the requirement described in the standard:</p> <p>Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate.</p> <p>Amplitude: 0.5 mv~5 mv</p> <p>In adult mode, these two signals are not responded:</p> <ol style="list-style-type: none"> <li>1. when QRS amplitude of 0.15 mV or less is applied;</li> <li>2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied.</li> </ol> <p>Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.</p> |
| <b>PVCs</b>                                |   |
|  |   |
| Range                                      | ADU:(0 to 300) PVCs/ min<br>PED/NEO: (0 to 350) PVCs/ min   |
| Resolution                                 | 1 PVCs/min (For display and alarm limit)  |
| <b>Pause/min</b>                           |   |
| Range                                      | ADU/PED/NEO: (0 to 30) pauses/min   |
| Resolution                                 | 1 pause/min (For display and alarm limit)   |
| <b>ST value</b>                            |   |
| Range                                      | -2.0 mV to +2.0 mV  |
| Accuracy                                   | -0.8 mV to +0.8 mV: $\pm 0.02 \text{ mV}$ or 10%, whichever is greater.<br>Beyond this range: not specified.  |
| Resolution                                 | 0.01 mV (For display and alarm limit)   |
| <b>QT measurement</b>                      |   |
| Range                                      | 200 ms ~ 800 ms   |
| Resolution                                 | 4 ms (For display)  |
| Accuracy                                   | $\pm 30 \text{ ms}$   |
| <b>QTc measurement</b>                     |   |
| Range                                      | 200ms ~ 800 ms  |
| Resolution                                 | 1 ms (For display and alarm limit)  |
| <b><math>\Delta QTc</math> measurement</b> |   |
| Range                                      | -600 ms ~ 600 ms  |
| Resolution                                 | 1 ms (For display and alarm limit)  |
| <b>HR Averaging Method</b>                 |   |
| Method 1                                   | Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.   |

|   |   |
|---|---|
| Method 2  | If each of three consecutive RR intervals is greater than 1200 ms, then the four most recent RR intervals are averaged to compute the HR.   |
| Range of Sinus and SV Rhythm                            |   |
| Tachy   | Adult: RR interval for 5 consecutive QRS complex $\leq 0.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\leq 0.375$ s.   |
| Normal  | Adult: $0.5 \text{ s} < \text{RR interval for 5 consecutive QRS complex} < 1.5 \text{ s}$ .<br>Pediatric/neonatal: $0.375 \text{ s} < \text{RR interval for 5 consecutive QRS complex} < 1 \text{ s}$ . |
| Brady   | Adult: RR interval for 5 consecutive QRS complex $\geq 1.5$ s.<br>Pediatric/neonatal: RR interval for 5 consecutive QRS complex $\geq 1$ s.   |
| Range of Ventricular Rhythm                             |   |
| V-Tach  | 5 consecutive ventricular beats and ventricular HR $\geq 100$ bpm.  |
| Vent Rhythm   | 5 consecutive ventricular beats, and $20 \text{ bpm} \leq \text{ventricular HR} < 40 \text{ bpm}$ .   |
| Vent Brady  | 5 consecutive ventricular beats, and ventricular HR $< 20$ bpm.   |
| Acc. Vent Rhythm  | 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$ .  |
| Maximum Start-up Alarm Time for Tachycardia             |   |
| V-Tach<br>(Ventricular<br>Tachycardia)<br>1 mV 206 bpm  | Gain 0.5: 10 s<br>Gain 1.0: 10 s<br>Gain 2.0: 10 s  |
| V-Tach<br>(Ventricular<br>Tachycardia)<br>2 mV 195 bpm  | Gain 0.5: 10 s<br>Gain 1.0: 10 s<br>Gain 2.0: 10 s  |
| Response Time of Heart<br>Rate Meter to Change in<br>HR | HR range: 80 bpm to 120 bpm<br>Range : Within 11 s<br>HR range: 80 bpm to 40 bpm<br>Range : Within 11 s   |
| ☆Tall T-wave Rejection                                  | Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude   |

|   |  |                |                   |
|---|--|----------------|-------------------|
| Accuracy of Heart Rate Meter and Response to Irregular Rhythm | Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows:<br>Ventricular bigeminy: 80 bpm±1 bpm<br>Slow alternating ventricular bigeminy: 60 bpm±1 bpm<br>Rapid alternating ventricular bigeminy: 120 bpm±1 bpm<br>Bidirectional systoles: 91 bpm±1 bpm |                |                   |
| Time to Alarm for Heart Rate alarm conditions                 | Asystole alarm: ≤ 10 s<br>HR low alarm: ≤ 10 s<br>HR high alarm: ≤ 10 s  |                |                   |
| Arrhythmia analysis   | Asystole   | V-Fib/V-Tach   | Couplet           |
|   | Vent Rhythm  | PVC Bigeminy   | PVC Trigeminy     |
|   | Tachy  | R on T         | PVC               |
|   | Irr Rhythm   | Brady          | Missed Beat       |
|   | Pacer not Pacing   | Vent Brady     | Pacer not Capture |
|   | VEB  | Run PVCs       | Acc. Vent Rhythm  |
|   | IPVC   | Non-Sustain VT | Multiform PVCs    |
|   | Pause/min High   | Pause          | Afib              |
|   | PAC Bigeminy   | PVCs High      | Low Voltage(Limb) |
|   | Extreme Brady  | PAC Trigeminy  | Wide QRS Tachy    |
|   | Sustain VT   | Extreme Tachy  | V-Tach            |

## A.5 RESP

|                                      |  |
|--------------------------------------|--|
| Method                               | Impedance between RA-LL, RA-LA                                   |
| Measurement lead                     | Options are lead I and II. The default is lead II.               |
| Calculation Type                     | Manual, Automatic  |
| Baseline Impedance Range             | 200 Ω to 2500 Ω (with ECG cables of 1 KΩ resistance)             |
| Measuring Sensitivity                | Within the baseline impedance range: 0.3 Ω                       |
| Waveform Bandwidth                   | 0.2 Hz to 3.3 Hz (-3 dB)   |
| Respiration Excitation Waveform      | Sinusoid, 45.6 kHz (±10%), < 350 μA                              |
| ☆Gain Selection                      | ×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5                                  |
| ☆Sweep                               | 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s                           |
| ☆No Breath Detected Alarm Time Setup | 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s. |
| ☆Measuring Range                     | 0 rpm ~ 200 rpm  |
| Resolution                           | 1 rpm (For display and alarm limit)                              |

|             |  |
|-------------|--|
| ☆Accuracy   | $\pm 1$ rpm (0 rpm~120 rpm)<br>$\pm 2$ rpm (121 rpm~200 rpm) |
| Update time | 1 s  |

## A.6 NIBP

Complies with IEC 80601-2-30.

|  |  |
|--|--|
| Technique                                      | Oscillometry   |
| Mode   | Manual, Auto, Continuous, Sequence   |
| Measuring Interval in AUTO Mode (unit: minute) | 1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define                 |
| Continuous                                     | 5 min, interval is 5 s   |
| Measuring Parameter                            | SYS, DIA, MAP, PR  |
| Pressure Unit                                  | kPa, mmHg, cmH <sub>2</sub> O  |
| ☆Measuring Range                               |  |
| ☆Adult Mode                                    | SYS: 25 mmHg to 290 mmHg<br>DIA: 10 mmHg to 250 mmHg<br>MAP: 15 mmHg to 260 mmHg |
| ☆Pediatric Mode                                | SYS: 25 mmHg to 240 mmHg<br>DIA: 10 mmHg to 200 mmHg<br>MAP: 15 mmHg to 215 mmHg |
| ☆Neonatal Mode                                 | SYS: 25 mmHg to 140 mmHg<br>DIA: 10 mmHg to 115 mmHg<br>MAP: 15 mmHg to 125 mmHg |
| ☆Alarm Type                                    | SYS, DIA, MAP  |
| ☆Cuff Pressure Measuring Range                 | 0 mmHg to 300 mmHg   |
| Pressure Resolution                            | 1 mmHg (For display and alarm limit)   |
| ☆Maximum Mean Error                            | $\pm 5$ mmHg   |
| ☆Maximum Standard Deviation                    | 8 mmHg   |
| Maximum Measuring Period                       |  |
| Adult/Pediatric                                | 120 s  |
| Neonate  | 90 s   |

|   |  |
|---|--|
| Typical Measuring Period                                | iCUFS measurement: 20 s to 35 s (depend on HR/motion disturbance) (measured with E9 cuff, default inflation value, PR is set as 80 bpm and systolic pressure within 100~120 mmHg)<br>iFAST measurement: 15 s (depend on SYS, arm circumference and HR/motion disturbance) (measured with E8 cuff, PR is set as 80 bpm and systolic pressure within 100~120 mmHg) |
| <b>Dual Independent Channel Overpressure Protection</b> |  |
| Adult   | (297±3) mmHg   |
| Pediatric   | (245±3) mmHg   |
| Neonatal  | (147±3) mmHg   |
| <b>Pre-inflation Pressure</b>                           |  |
| Adult   | 80/100/120/140/150/160/180/200/220/240 mmHg  |
| Pediatric   | 80/100/120/140/150/160/180/200 mmHg  |
| Neonatal  | 60/70/80/100/120 mmHg  |
| <b>Venipuncture pressure</b>                            |  |
| Adult   | Default: 80 mmHg<br>Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 110 mmHg, 120 mmHg  |
| Pediatric   | Default: 60 mmHg<br>Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg   |
| Neonatal  | Default: 40 mmHg<br>Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg  |

**A.7 SpO<sub>2</sub>**

Complies with ISO 80601-2-61.

|                      |  |
|----------------------|--|
| Measuring Range      | 0% to 100%   |
| Resolution           | 1% (For display and alarm limit)   |
| ☆ Data Update Period | 1 s  |
| ☆ Accuracy           |  |
| ☆ Adult /Pediatric   | ±2% (70% to 100% SpO <sub>2</sub> )<br>Undefined (0% to 69% SpO <sub>2</sub> ) |
| ☆ Neonate            | ±3% (70% to 100% SpO <sub>2</sub> )<br>Undefined (0% to 69% SpO <sub>2</sub> ) |

| Sensor               |   |
|----------------------|---|
| Red Light            | (660±3) nm  |
| Infrared Light       | (905±10) nm   |
| Emitted Light Energy | < 15 mW   |
| PI                   |   |
| Measuring Range      | 0.05% to 20%, invalid PI value is -?--, measurement error is not defined. |
| Resolution           | 0.01% (0.05%-9.99%)<br>0.1% (10.0%-20.0%)                                 |

NOTE: The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

### A.8 PR

| Parameter               | Measuring range   | Accuracy   | Resolution                          |
|-------------------------|-------------------|--|-------------------------------------|
| ☆PR (SpO <sub>2</sub> ) | 20 bpm to 300 bpm | ±2 bpm   | 1 bpm (For display and alarm limit) |
| ☆PR (NIBP)              | 40 bpm to 240 bpm | ±3 bpm or 3.5%, whichever is greater   | 1 bpm (For display)                 |
| ☆PR (IBP)               | 20 bpm to 300 bpm | ±2 bpm or ±2%, whichever is greater (30 bpm to 300 bpm);<br>Undefined (20 bpm to 29 bpm) | 1 bpm (For display and alarm limit) |

### A.9 TEMP

Complies with ISO 80601-2-56.

|  |  |
|--|--|
| Technique                                | Thermal resistance                             |
| Position                                 | Skin, cavity                                   |
| Measure Parameter                        | T1, T2, TD (the absolute value of T2 minus T1) |
| Channel                                  | 2  |
| Sensor Type                              | YSI-10K and YSI-2.252K                         |
| Unit                                     | °C, °F   |
| Measuring Range                          | 0 °C to 50 °C(32 °F to 122 °F)                 |
| Resolution (For display and alarm limit) | 0.1 °C (0.1 °F)                                |
| ☆Accuracy <sup>1</sup>                   | ±0.1 °C  |
| Refresh Time                             | Every 1 s to 2 s                               |
| Temperature Calibration                  | At an interval of 5 to 10 minutes              |
| Measuring Mode                           | Direct Mode                                    |
| Transient Response Time                  | ≤ 30 s   |

## A.10 IBP

Complies with IEC 60601-2-34.

|                            |  |  |
|----------------------------|--|--|
| Technique                  |  | Direct invasive measurement                    |
| Channel                    |  | 2 channels                                     |
| IBP Measure                | ★Measuring Range                         | (-50 to +360) mmHg                             |
|                            | Resolution (For display and alarm limit) | 1 mmHg (For display and alarm limit)           |
|                            | ★Accuracy (not including sensor)         | ±2% or ±1 mmHg, whichever is greater           |
| PPV                        | ★Measuring Range                         | 0%~50%   |
| Pressure Unit              |  | kPa, mmHg, cmH <sub>2</sub> O                  |
| Pressure sensor            |  |  |
| Sensitivity                |  | 5 µV/V/mmHg                                    |
| Impedance Range            |  | 300 Ω to 3000 Ω                                |
| Filter                     |  | DC~ 12.5 Hz; DC~ 40 Hz                         |
| Zero                       |  | Range: ±200 mmHg                               |
| Pressure Calibration Range | IBP (excluding ICP)                      | 80 mmHg to 300 mmHg                            |
|                            | ICP                                      | 80 mmHg to 300 mmHg                            |
| Volume Displacement        |  | 7.4 x 10 <sup>4</sup> mm <sup>3</sup> /100mmHg |

## A.11 C.O.

|  |   |
|--|---|
| Technique                                | Thermodilution Technique                  |
| Measure Parameters                       | C.O., TB, TI                              |
| Measuring Range                          |   |
| C.O.                                     | 0.1 L/min to 20 L/min                     |
| TB                                       | 23 °C to 43 °C (73.4 °F to 109.4 °F)      |
| TI                                       | -1 °C to 27 °C (30.2 °F to 80.6 °F)       |
| Resolution (For display and alarm limit) |   |
| C.O.                                     | 0.1 L/min                                 |
| TB, TI                                   | +0.1 °C (+0.1 °F)                         |
| Accuracy                                 |   |
| C.O.                                     | ±5% or ± 0.2 L/min                        |
| TB                                       | ±0.1 °C (±0.18 °F) (not including sensor) |
| TI                                       | ±0.1 °C (±0.18 °F) (not including sensor) |

NOTE: At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

## A.12 CO<sub>2</sub>

Complies with ISO 80601-2-55.

|  |   |   |   |
|--|---|---|---|
| Intended Patient                         | Adult, pediatric, neonatal  |   |   |
| Measure Parameters                       | etCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR                                  |   |   |
| Unit                                     | mmHg, %, kPa  |   |   |
| ★Measuring Range                         | etCO <sub>2</sub>   | 0 mmHg to 152 mmHg                        |   |
|  | FiCO <sub>2</sub>   | 0 mmHg to 50 mmHg                         |   |
|  | AwRR  | 0 rpm to 150 rpm                          |   |
| Resolution (For display and alarm limit) | etCO <sub>2</sub>   | 1 mmHg (For display and alarm limit)      |   |
|  | FiCO <sub>2</sub>   | 1 mmHg (For display and alarm limit)      |   |
|  | AwRR  | 1 rpm (For display and alarm limit)       |   |
| ★Accuracy                                | etCO <sub>2</sub>   | 0 mmHg to 40 mmHg:<br>± 2 mmHg            | Measurement conditions:<br>Ambient temperature: (25 ± 3)<br>°C        |
|  |   | 41 mmHg to 70 mmHg:<br>± 5% of reading    | Barometric pressure: (760± 10)<br>mmHg                                |
|  |   | 71 mmHg to 100 mmHg:<br>± 8% of reading   | Balance gas: N <sub>2</sub>   |
|  |   | 101 mmHg to 150 mmHg:<br>± 10% of reading | Sample gas flowrate: 100<br>ml/min<br>I/E ratio: 1:2<br>AwRR ≤ 80 rpm |
|  | AwRR  | ±1 rpm                                    |   |
| Drift of Measure Accuracy                | Meets the requirements of the measure accuracy                                |   |   |
| Sample Gas Flowrate                      | 50 ml/min, 70 ml/min or 100 ml/min (optional), accuracy: ±15 ml/min           |   |   |
| Warm-up Time                             | Display reading within 20 s; reach to the designed accuracy within 2 minutes. |   |   |
| Rise Time                                | < 400 ms (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)        |   |   |
|  | < 500 ms (with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)         |   |   |
|  | < 1000 ms (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)        |   |   |
| Response Time                            | < 4 s (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min&70 ml/min) |   |   |

|                                       |   |   |
|---------------------------------------|---|---|
|                                       | < 5.5 s (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)  |   |
| Work Mode                             | Standby (default), measure  |   |
| O <sub>2</sub> Compensation           | Range: 0% to 100%<br>Resolution: 1%<br>Default: 16%   |   |
| N <sub>2</sub> O Compensation         | Range: 0% to 100%<br>Resolution: 1%<br>Default: 0%  |   |
| AG Compensation                       | Range: 0% to 20%<br>Resolution: 0.1%<br>Default: 0%   |   |
| Humidity Compensation Method          | ATPD (default), BTPS  |   |
| Barometric Pressure Compensation      | Automatic (The change of barometric pressure will not add additional errors to the measurement values.)   |   |
| Zero Calibration                      | Support   |   |
| Calibration                           | Support (It is recommend to be operated by trained personal.)   |   |
| ☆Alarm                                | etCO <sub>2</sub> , FiCO <sub>2</sub> , AwRR  |   |
| ☆No Breath Detected Alarm Delay       | 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.  |   |
| Data Sample Rate                      | 100 Hz  |   |
| etCO <sub>2</sub> Change <sup>1</sup> | AwRR ≤ 80 rpm, meet the accuracy mentioned above;<br>AwRR > 80 rpm, etCO <sub>2</sub> descends 8%;<br>AwRR > 120 rpm, etCO <sub>2</sub> descends 10%  | with 2 m gas sampling tube,<br>sample gas flowrate: 100 ml/min) |
|                                       | AwRR ≤ 60 rpm, meet the accuracy mentioned above;<br>AwRR > 60 rpm, etCO <sub>2</sub> descends 8%;<br>AwRR > 90 rpm, etCO <sub>2</sub> descends 10%;<br>AwRR > 120 rpm, etCO <sub>2</sub> descends 15%; | with 2 m gas sampling tube,<br>sample gas flowrate: 70 ml/min)  |

|  |   |  |
|--|---|--|
|  | AwRR $\leq$ 20 rpm, meet the accuracy mentioned above;<br>AwRR > 20 rpm, etCO <sub>2</sub> descends 8%;<br>AwRR > 40 rpm, not applicable; | with 2 m gas sampling tube,<br>sample gas flowrate: 50 ml/min) |
|--|---|--|

Note 1: Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and end-tidal reading change refers to the nominal value.

#### Interfering Gas Effects:

| Gas                              | Gas Level (%)  | Quantitative Effect/Comments |
|----------------------------------|----------------|------------------------------|
| Nitrous oxide                    | 60%            | None                         |
| Halothane                        | 4%             | None                         |
| Enflurane                        | 5%             | None                         |
| Isoflurane                       | 5%             | None                         |
| Sevoflurane                      | 5%             | None                         |
| Xenon                            | Not applicable | Not applicable               |
| Hehelium                         | Not applicable | Not applicable               |
| Metered dose inhaler propellants | Not applicable | Not applicable               |
| Desflurane                       | 15%            | None                         |
| Ethanol                          | 0.1%           | None                         |
| Isopropanol                      | 0.1%           | None                         |
| Acetone                          | 0.1%           | None                         |
| Methane                          | 1%             | None                         |

## A.13 Interfaces

| Interface Name                | Interface Type | Interface Quantity | Interface Specification   | Note |
|-------------------------------|----------------|--------------------|---|------|
| Analog Output                 | Output         | 1                  | Output analog signal.   |      |
| Defibrillator Synchronization | Output         | 1                  | Output synchronous defibrillation signal.   |      |
| Nurse Call                    | Output         | 1                  | Support nurse call.   |      |
| USB Interfaces                | Input, Output  | 2                  | 1. Support the connection of barcode scanner;<br>2. Support connection to external removable storage devices for external data storage. |      |
| Video Output Interface        | Output         | 1                  | Video Output (HDMI)   |      |

| Interface Name     | Interface Type | Interface Quantity | Interface Specification  | Note   |
|--------------------|----------------|--------------------|--|--------|
| Ethernet interface | Input, Output  | 1                  | RJ45 interface, with light<br>Used to connect other systems and system upgrades in the network | TCP/IP |
| AC power interface | Input          | 1                  | AC external power supply   |        |
| Wi-Fi              | Input, Output  | 1                  | Support 2.4 GHz WIFI, 5 GHz WIFI   |        |

### A.13.1 ECG Analog Output

|   |  |
|---|--|
| Bandwidth (-3 dB; reference frequency: 10 Hz) | Diagnosis: 0.05 Hz to 150 Hz<br>Monitor and Monitor (Hi-Fi): 0.5 Hz to 40 Hz<br>ST: 0.05 Hz to 40 Hz<br>Surgery: 1 Hz to 20 Hz<br>Enhanced: 2 Hz ~18 Hz<br>Customized: When Low-pass Filter < 40 Hz, Bandwidth is High-pass Filter ~ Low-pass Filter; When Low-pass Filter > 40 Hz, Bandwidth is High-pass ~40 Hz. |
| Maximum Transmission Delay (Diagnosis Mode)   | 500 ms   |
| Sensitivity                                   | 1 V/1 mV ±10%  |
| Pace Rejection/ Enhancement                   | Provide pace rejection, but no pace enhancement  |
| Waveform Display                              | Consistent with ECG1.  |
| Compliant with Standard and Directive         | Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.  |
| Output Impedance                              | < 500 Ω  |
| Interface Type                                | PS2 connector  |

NOTE:

While using analog output, set the calculation lead as following:

- 1) In 3 Electrodes mode, set to Lead I, Lead II, or Lead III.
- 2) In 5 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V.
- 3) In 6 Electrodes mode, set to I, II, III, and leads corresponding to Va, Vb.
- 4) In 10 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V1~V6.

### A.13.2 Defibrillator Synchronization

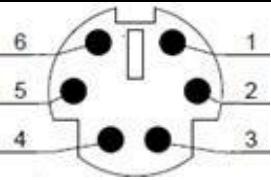
|                    |  |
|--------------------|--|
| Output Impedance   | < 500 Ω                                      |
| Maximum Time Delay | 35 ms (R-wave peak to leading edge of pulse) |
| Waveform           | Rectangular wave                             |

|                                   |  |
|-----------------------------------|--|
| Amplitude                         | High level: 3.5 V to 5.5 V, providing a maximum of 1 mA output current;<br>Low level: < 0.5 V, receiving a maximum of 5 mA input current |
| Minimum Required R-wave Amplitude | 0.3 mV   |
| Pulse Width                       | 100 ms±10%   |
| Limited Current                   | 15 mA rating   |
| Rising and Falling Time           | < 1 ms   |
| Interface Type                    | PS2 connector  |

### A.13.3 Nurse Call

|                  |                                    |
|------------------|------------------------------------|
| Drive Mode       | Voltage output                     |
| Power Supply     | ≤ 12.6 VDC, 200 mA Max.            |
| Interface Signal | 12 V power supply and PWM waveform |
| Interface Type   | PS2 connector                      |

PS2 connector Definition for Analog Output/Defibrillator Synchronization/Nurse Call

|  | PIN.NO. | Signal name | Signal Description                   |
|---|---------|-------------|--------------------------------------|
|   | 1       | ANALOG_OUT  | Analog out signal                    |
|   | 2       | GND         | Ground                               |
|   | 3       | SYS_OUT     | Defibrillator Synchronization signal |
|   | 4       | +12V        | Nurse call power                     |
|   | 5       | GND         | Ground                               |
|   | 6       | NURSE_OUT   | Nurse call control signal            |

### A.13.4 USB Interfaces

|                          |                                     |
|--------------------------|-------------------------------------|
| Number of USB Interfaces | Standard: 2                         |
| Drive Mode               | HOST interface, USB1.0/2.0 protocol |
| Power Supply             | 5 VDC±5%, 500 mA Max.               |
| Interface Type           | USB A-type port                     |

### A.13.5 Video Output Interface

|                |                  |
|----------------|------------------|
| Interface Type | HDMI A-type port |
|----------------|------------------|

### A.13.6 Wired Network Interface

|                |                                  |
|----------------|----------------------------------|
| Specification  | 100-Base TX (IEEE802.3)          |
| Interface Type | Standard RJ-45 network interface |

## B EMC Information

### - Guidance and Manufacture's Declaration

#### B.1 Electromagnetic Emissions

| Guidance and manufacture's declaration – electromagnetic emission |            |  |
|---|------------|--|
| Emission test   | Compliance | Electromagnetic environment – guidance   |
| RF emissions<br>CISPR 11  | Group 1    | CX Series use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  |
| RF emission<br>CISPR 11   | Class A    | CX Series are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC/EN 61000-3-2                            | Class A    |  |
| Voltage fluctuations/<br>flicker emissions<br>IEC/EN 61000-3-3    | Complies   |  |

NOTE: The EMISSIONS characteristics of CX Series make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) CX Series might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

#### B.2 Electromagnetic Immunity

| Guidance and manufacture's declaration – electromagnetic immunity   |
|---|
| CX Series are intended for use in the electromagnetic environment specified below. The customer or the user of CX Series should assure that they are used in such an environment. |

| Immunity test   | IEC/EN 60601 test level   | Compliance level  | Electromagnetic environment - guidance   |
|---|---|---|--|
| Electrostatic discharge (ESD)<br>IEC/EN 61000-4-2   | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air  | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV air  | Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.   |
| Electrical fast transient/burst<br>IEC/EN 61000-4-4   | ±2 kV for power supply lines  | ±2kV for power supply lines   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC/EN 61000-4-5   | ±1 kV for line to line<br>±2 kV for line to ground  | ±1 kV for line to line<br>±2 kV for line to ground  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Power frequency (50/60 Hz) magnetic field<br>IEC/EN 61000-4-8   | 30 A/m  | 30 A/m  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC/EN 61000-4-11 | 0 % U <sub>T</sub> ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % U <sub>T</sub> ; 1 cycle and<br>70 % U <sub>T</sub> ; 25/30 cycles )<br><br>Single phase: at 0°<br><br>0 % U <sub>T</sub> ; 250/300 cycle | 0 % U <sub>T</sub> ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % U <sub>T</sub> ; 1 cycle and<br>70 % U <sub>T</sub> ; 25/30 cycles )<br><br>Single phase: at 0°<br><br>0 % U <sub>T</sub> ; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of CX Series requires continued operation during power mains interruptions, it is recommended that CX Series be powered from an uninterruptible power supply or a battery. |

|                                       |   |   |    |
|---------------------------------------|---|---|----|
| IMMUNITY to proximity magnetic fields | Test frequency: 30 KHz; 65 A/m,<br>Modulation: Pulse modulation, 2.1KHz<br><br>Test frequency: 134.2 KHz;<br>7.5 A/m,<br>Modulation: Pulse modulation, 50 KHz<br><br>Test frequency: 13.56 MHz; | Test frequency: 30 KHz; 65 A/m,<br>Modulation: Pulse modulation, 2.1 KHz<br><br>Test frequency: 134.2 KHz; 7.5 A/m,<br>Modulation: Pulse modulation, 50 KHz<br><br>Test frequency: 13.56 MHz; | -- |
|---------------------------------------|---|---|----|

NOTE U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.

### Test Levels

| RFID Specification                   | Frequency   | Test level (RMS) | Result   |
|--------------------------------------|-------------|------------------|----------|
| ISO 14223                            | 134.2 kHz   | 65 A/m           | Complies |
| ISO/IEC 14443-3 (Type A)             | 13.56 MHz   | 7.5 A/m          | Complies |
| ISO/IEC 14443-4 (Type B)             | 13.56 MHz   | 7.5 A/m          | Complies |
| ISO/IEC 15693 (ISO 18000-3 Mode 1)   | 13.56 MHz   | 5 A/m            | Complies |
| ISO 18000-3 Mode 3                   | 13.56 MHz   | 12 A/m           | Complies |
| ISO/IEC 18000-7                      | 433 MHz     | 3 V/m            | Complies |
| ISO/IEC 18000-63 Type C <sup>a</sup> | 860-960 MHz | 54 V/m           | Complies |
| ISO/IEC 18000-4 Mode 1               | 2.45 GHz    | 54 V/m           | Complies |

NOTE: Keep RFID readers away from the device.

### B.3 Electromagnetic Immunity

| Guidance and manufacturer's declaration – electromagnetic immunity  |                         |                  |   |
|---|-------------------------|------------------|---|
| CX Series are intended for use in the electromagnetic environment specified below. The customer or the user of CX Series should assure that they are used in such an environment. |                         |                  |   |
| Immunity test   | IEC/EN 60601 test level | Compliance level | Electromagnetic environment - guidance  |
|   |                         |                  | Portable and mobile RF communications equipment should be used no closer to any part of CX Series, including cables, than the recommended separation distance |

|                                     |  |  |   |
|-------------------------------------|--|--|---|
| Conducted RF<br>IEC/EN<br>61000-4-6 | 3 V <sub>rms</sub><br>150 kHz to 80 MHz<br>6Vrms <sup>c</sup> in ISM bands | 3 V <sub>rms</sub><br>150 kHz to 80 MHz  | calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = 1.2 \sqrt{P}$ 150KHz to 80MHz   |
| Radiated RF<br>IEC/EN<br>61000-4-3  | between<br>0.15 MHz and 80<br>MHz<br>3 V/m<br>80 MHz to 2.7 GHz            | 6Vrms <sup>c</sup> in ISM<br>bands<br>between<br>0.15 MHz and<br>80 MHz<br>3 V/m<br>80 MHz to 2.7<br>GHz | $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz<br>$d = 6 \sqrt{P/E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer).<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
|                                     | See Table 1  | Comply with<br>Table 1   |   |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is

|  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|
| affected by absorption and reflection from structures, objects and people.   |  |  |  |  |  |  |
| <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which CX Series are used exceeds the applicable RF compliance level above, CX Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating CX Series. |  |  |  |  |  |  |
| <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.   |  |  |  |  |  |  |
| <sup>c</sup> The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.  |  |  |  |  |  |  |

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

| Test frequency (MHz) | Band <sup>a)</sup> (MHz) | Service <sup>a)</sup> | Modulation <sup>b)</sup>                            | Maximum power (W) | Distance (m) | Immunity test level (V/m) |
|----------------------|--------------------------|-----------------------|---|-------------------|--------------|---------------------------|
| 385                  | 380-390                  | TETRA 400             | Pulse modulation <sup>b)</sup><br>18 Hz             | 1.8               | 0.3          | 27                        |
| 450                  | 430-470                  | GMRS 460,<br>FRS 460  | FM <sup>c)</sup><br>± 5 kHz deviation<br>1 kHz sine | 2                 | 0.3          | 28                        |
| 710                  |                          |                       |   |                   |              |                           |
| 745                  |                          |                       |   |                   |              |                           |
| 780                  |                          |                       |   |                   |              |                           |
| 810                  |                          |                       |   |                   |              |                           |
| 870                  |                          |                       |   |                   |              |                           |
| 930                  |                          |                       |   |                   |              |                           |

| Test frequency (MHz)   | Band <sup>a)</sup> (MHz) | Service <sup>a)</sup>  | Modulation <sup>b)</sup>                    | Maximum power (W) | Distance (m) | Immunity test level (V/m) |  |  |  |  |  |  |
|--|--------------------------|--|---|-------------------|--------------|---------------------------|--|--|--|--|--|--|
| 1720   | 1700-1990                | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT; LTE<br>Band 1, 3, 4,<br>25; UMTS | Pulse<br>modulation <sup>b)</sup><br>217 Hz | 2                 | 0.3          | 28                        |  |  |  |  |  |  |
| 1845   |                          |  |   |                   |              |                           |  |  |  |  |  |  |
| 1970   |                          |  |   |                   |              |                           |  |  |  |  |  |  |
| 2450   | 2400-2570                | Bluetooth,<br>WLAN,<br>802.11 b/g/n,<br>RFID 2450,<br>LTE Band 7               | Pulse<br>modulation <sup>b)</sup><br>217 Hz | 2                 | 0.3          | 28                        |  |  |  |  |  |  |
| 5240   | 5100-5800                | WLAN 802.11<br>a/n   | Pulse<br>modulation <sup>b)</sup><br>217 Hz | 0.2               | 0.3          | 9                         |  |  |  |  |  |  |
| 5500   |                          |  |   |                   |              |                           |  |  |  |  |  |  |
| 5785   |                          |  |   |                   |              |                           |  |  |  |  |  |  |
| NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.  |                          |  |   |                   |              |                           |  |  |  |  |  |  |
| a) For some services, only the uplink frequencies are included.<br>b) The carrier shall be modulated using a 50 % duty cycle square wave signal.<br>c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. |                          |  |   |                   |              |                           |  |  |  |  |  |  |

#### B.4 Recommended Separation Distances

| Recommended separation distances between portable and mobile RF communications equipment and CX Series |  |   |  |
|--|--|---|--|
| Rated maximum output power of transmitter (W)  | Separation distance according to frequency of transmitter(m) |   |  |
|  | 150 kHz to 80 MHz<br>$d = 1.2 \text{ } P$                    | 80 MHz to 800 MHz<br>$d = 1.2 \text{ } P$ | 800 MHz to 2.7 GHz<br>$d = 2.3 \text{ } P$ |
| 0.01   | 0.12   | 0.12                                      | 0.23                                       |
| 0.1  | 0.38   | 0.38                                      | 0.73                                       |

|    |     |     |     |
|----|-----|-----|-----|
| 1  | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 10 | 12  | 12  | 23  |

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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## C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

NOTE: If your monitor has been preconfigured according to your requirements, the settings at delivery will be different from the default settings listed here.

### C.1 Patient Information Default Settings

| Patient Information Settings |         |
|------------------------------|---------|
| Patient Type                 | Adult   |
| Pace                         | Unknown |

### C.2 Alarm Default Settings

| Alarm Settings        |               |
|-----------------------|---------------|
| Pause Time            | 120 s         |
| Alarm Latch           | OFF           |
| Alarm Light           | ON When Reset |
| Alarm Switch Setup    | Enable        |
| Alarm Reset Authority | OFF           |

### C.3 ECG Default Settings

| ECG Settings                        | Adult  | Pediatric | Neonate |
|-------------------------------------|--------|-----------|---------|
| Alarm Switch                        | ON     |           |         |
| Alarm Record                        | OFF    |           |         |
| Alarm Level                         | Medium |           |         |
| Alarm High Limit                    | 120    | 160       | 200     |
| Alarm Low Limit                     | 50     | 75        | 100     |
| Arrhythmia Analysis Threshold Value |        |           |         |
| Low Voltage(Limb)                   | 0.5 mV |           |         |
| Pause                               | 3 s    |           |         |
| Sustain VT                          | 30 s   |           |         |
| PAC Bigeminy                        | 8/min  |           |         |
| Pause/min High                      | 8/min  |           |         |
| PVCs High                           | 10/min |           |         |
| PAC Trigeminy                       | 16/min |           |         |
| ExtremeTachy                        | 160    | 180       | 200     |
| Extreme Brady                       | 30     | 50        | 60      |

|  |         |     |     |
|--|---------|-----|-----|
| Pace   | OFF     |     |     |
| Electrode Type   | Auto    |     |     |
| Filter   | Monitor |     |     |
| Smart Lead Off   | ON      |     |     |
| QRS Volume   | 2       |     |     |
| ST Analysis  | OFF     |     |     |
| Alarm Switch   | ON      |     |     |
| Alarm Level  | Medium  |     |     |
| Alarm Record   | OFF     |     |     |
| Alarm High Limit<br>(ST-X)   | 0.20    |     |     |
| Alarm Low Limit<br>(ST-X)  | -0.20   |     |     |
| QT Analysis  | OFF     |     |     |
| QTc  | 500     | 480 | 460 |
| ΔQTc   | 60      |     |     |
| X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6. |         |     |     |
| Arrhythmia Analysis  | ON      | OFF | OFF |

| Arrhythmia Alarm<br>Settings | Alarm Switch       | Alarm Level          | Alarm Record |
|------------------------------|--------------------|----------------------|--------------|
| Asystole                     | ON(non-adjustable) | High(non-adjustable) | OFF          |
| V-Fib/V-Tach                 | ON                 | High(non-adjustable) | OFF          |
| R on T                       | ON                 | Medium               | OFF          |
| PVC                          | ON                 | Low                  | OFF          |
| Couplet                      | ON                 | Low                  | OFF          |
| Run PVCs                     | ON                 | Low                  | OFF          |
| PVC Bigeminy                 | ON                 | Low                  | OFF          |
| PVC Trigeminy                | ON                 | Low                  | OFF          |
| Tachy                        | ON                 | Medium               | OFF          |
| Brady                        | ON                 | Medium               | OFF          |
| Missed Beat                  | ON                 | Low                  | OFF          |
| Irr Rhythm                   | ON                 | Low                  | OFF          |
| Pacer not Capture            | ON                 | Medium               | OFF          |
| Pacer not Pacing             | ON                 | Medium               | OFF          |
| Vent Brady                   | ON                 | High(non-adjustable) | OFF          |
| Vent Rhythm                  | ON                 | Medium               | OFF          |
| Sustain VT                   | ON(non-adjustable) | High(non-adjustable) | OFF          |

| Arrhythmia Alarm Settings | Alarm Switch | Alarm Level          | Alarm Record |
|---------------------------|--------------|----------------------|--------------|
| ExtremeTachy              | ON           | High(non-adjustable) | OFF          |
| ExtremeBrady              | ON           | High(non-adjustable) | OFF          |
| V-Tach                    | ON           | High(non-adjustable) | OFF          |
| Wide QRS Tachy            | ON           | Medium               | OFF          |
| Non-Sustain VT            | ON           | Medium               | OFF          |
| Afib                      | ON           | Medium               | OFF          |
| Acc. Vent Rhythm          | ON           | Low                  | OFF          |
| Pause                     | ON           | Medium               | OFF          |
| Pause/min High            | ON           | Medium               | OFF          |
| PVCs High                 | ON           | Medium               | OFF          |
| VEB                       | ON           | Low                  | OFF          |
| Multiform PVCs            | ON           | Low                  | OFF          |
| IPVC                      | ON           | Low                  | OFF          |
| PAC Bigeminy              | ON           | Low                  | OFF          |
| PAC Trigeminy             | ON           | Low                  | OFF          |
| Low Voltage(Limb)         | ON           | Low                  | OFF          |

#### C.4 RESP Default Settings

| RESP Settings                 | Adult           | Pediatric | Neonate |
|-------------------------------|-----------------|-----------|---------|
| Alarm Switch                  | ON              |           |         |
| Alarm Record                  | OFF             |           |         |
| Alarm Level                   | Medium          |           |         |
| Alarm High Limit              | 30              | 30        | 100     |
| Alarm Low Limit               | 8               | 8         | 30      |
| No Breath Detected Alarm Time | 20 s            |           |         |
| Hold Type                     | Auto            |           |         |
| RR Source                     | CO <sub>2</sub> |           |         |
| Resp Lead                     | II              |           |         |
| Sweep                         | 12.5 mm/s       |           |         |
| Scale                         | x1              |           |         |

#### C.5 SpO<sub>2</sub> Default Settings

| SpO <sub>2</sub> Settings | Adult | Pediatric | Neonate |
|---------------------------|-------|-----------|---------|
| Alarm Switch              | ON    |           |         |
| Alarm Record              | OFF   |           |         |

|                              |           |     |    |
|------------------------------|-----------|-----|----|
| Alarm Level                  | Medium    |     |    |
| Alarm High Limit             | 100       | 100 | 98 |
| Alarm Low Limit              | 90        | 90  | 88 |
| Pitch Tone                   | OFF       |     |    |
| Sensitivity                  | Medium    |     |    |
| NIBP Simul                   | OFF       |     |    |
| Sweep                        | 12.5 mm/s |     |    |
| SpO <sub>2</sub> Desat Limit | 80%       |     |    |
| Sensor Light Intensity       | OFF       |     |    |

## C.6 PR Default Settings

| PR Settings      | Adult            | Pediatric | Neonate |
|------------------|------------------|-----------|---------|
| PR Source        | SpO <sub>2</sub> |           |         |
| Alarm Switch     | ON               |           |         |
| Alarm Record     | OFF              |           |         |
| Alarm Level      | Medium           |           |         |
| Alarm High Limit | 120              | 160       | 200     |
| Alarm Low Limit  | 50               | 75        | 100     |
| QRS Volume       | 2                |           |         |
| Alarm Source     | Auto             |           |         |

## C.7 NIBP Default Settings

| NIBP Settings          | Adult  | Pediatric | Neonate |
|------------------------|--------|-----------|---------|
| Alarm Switch           | ON     |           |         |
| Alarm Record           | OFF    |           |         |
| Alarm Level            | Medium |           |         |
| Alarm High Limit (SYS) | 160    | 120       | 90      |
| Alarm Low Limit (SYS)  | 90     | 70        | 40      |
| Alarm High Limit (Map) | 110    | 90        | 70      |
| Alarm Low Limit (Map)  | 60     | 50        | 30      |
| Alarm High Limit (Dia) | 90     | 70        | 60      |
| Alarm Low Limit (Dia)  | 50     | 40        | 20      |
| Inflation value        | 160    | 140       | 100     |
| Unit                   | mmHg   |           |         |
| Measure Mode           | Manual |           |         |
| NIBP Algorithm         | iCUFS  |           |         |

## C.8 TEMP Default Settings

| TEMP Settings         | Adult  | Pediatric | Neonate |
|-----------------------|--------|-----------|---------|
| Alarm Switch          | ON     |           |         |
| Alarm Record          | OFF    |           |         |
| Alarm Level           | Medium |           |         |
| Alarm High Limit (T1) | 39.0   | 39.0      | 39.0    |
| Alarm Low Limit (T1)  | 36.0   | 36.0      | 36.0    |
| Alarm High Limit (T2) | 39.0   | 39.0      | 39.0    |
| Alarm Low Limit (T2)  | 36.0   | 36.0      | 36.0    |
| Alarm High Limit (TD) | 2.0    | 2.0       | 2.0     |
| Unit                  | °C     |           |         |
| Measurement Site      | Skin   |           |         |

## C.9 IBP Default Settings

| IBP Settings   | Adult         | Pediatric     | Neonate       |
|--|---------------|---------------|---------------|
| Alarm Switch   | ON            |               |               |
| Alarm Record   | OFF           |               |               |
| Alarm Level  | Medium        |               |               |
| Unit   | mmHg          |               |               |
| Filter   | 12.5 Hz       |               |               |
|  | SYS, DIA, MAP | SYS, DIA, MAP | SYS, DIA, MAP |
| Alarm High Limit (ART, Ao, UAP, BAP, FAP, LV, P1-P4) | 160, 90, 110  | 120, 70, 90   | 90, 60, 70    |
| Alarm Low Limit (ART, Ao, UAP, BAP, FAP, LV, P1-P4)  | 90, 50, 70    | 70, 40, 50    | 50, 20, 35    |
| Alarm High Limit (PA)                                | 30, 16, 20    | 60, 4, 26     | 60, 4, 26     |
| Alarm Low Limit (PA)                                 | 10, 0, 0      | 24, -4, 12    | 24, -4, 12    |
|  | MAP           | MAP           | MAP           |
| Alarm High Limit (CVP, ICP, LAP, RAP, UVP)           | 10            | 4             | 4             |
| Alarm Low Limit (CVP, ICP, LAP, RAP, UVP)            | 0             | 0             | 0             |

## C.10 C.O. Default Settings

| C.O. Settings | Adult |
|---------------|-------|
| Alarm Switch  | ON    |
| Alarm Record  | OFF   |

|                              |        |
|------------------------------|--------|
| Alarm Level                  | Medium |
| Alarm High Limit (TB)        | 40     |
| Alarm Low Limit (TB)         | 30     |
| Injective Temperature Source | Auto   |
| Temperature Unit             | °C     |
| Interval                     | 70     |
| Constant                     | 0.542  |

### C.11 CO<sub>2</sub> Default Settings

| CO <sub>2</sub> Settings              | Adult     | Pediatric | Neonate |
|---------------------------------------|-----------|-----------|---------|
| Alarm Switch                          | ON        |           |         |
| Alarm Record                          | OFF       |           |         |
| Alarm Level                           | Medium    |           |         |
| Work Mode                             | Standby   |           |         |
| Unit                                  | mmHg      |           |         |
| No Breath Detected Alarm Time         | 20 s      |           |         |
| O <sub>2</sub> Compensation           | 16%       |           |         |
| N <sub>2</sub> O Compensation         | 0%        |           |         |
| Anes Agent                            | 0%        |           |         |
| Alarm High Limit (etCO <sub>2</sub> ) | 50        | 50        | 45      |
| Alarm Low Limit (etCO <sub>2</sub> )  | 25        | 25        | 30      |
| Alarm High Limit (FiCO <sub>2</sub> ) | 4         | 4         | 4       |
| Alarm High Limit (AwRR)               | 30        | 30        | 100     |
| Alarm Low Limit (AwRR)                | 8         | 8         | 30      |
| Sweep                                 | 6.25 mm/s |           |         |
| Amplitude                             | Low       |           |         |

## D Abbreviations

| Abbr               | English Full Name/Description                         |
|--------------------|---|
| AC                 | Alternating Current                                   |
| Acc. Vent Rhythm   | Accelerated Idioventricular Rhythm                    |
| Adu                | Adult   |
| Afib               | Atrial Fibrillation                                   |
| AG                 | Anaesthesia Gas                                       |
| Art                | Arterial  |
| aVF                | Left Foot Augmented Lead                              |
| aVL                | Left Arm Augmented Lead                               |
| aVR                | Right Arm Augmented Lead                              |
| AwRR               | Airway Respiration Rate                               |
| BP                 | Blood Pressure  |
| Brady              | Bradycardia   |
| BTPS               | Body temperature and pressure, saturated              |
| CI                 | Cardiac Index   |
| C.O.               | Cardiac Output  |
| CISPR              | International Special Committee on Radio Interference |
| CMS                | Central Monitoring System                             |
| CO <sub>2</sub>    | Carbon Dioxide  |
| COHb               | Carboxyhemoglobin                                     |
| Couplet            | Ventricular Couplets                                  |
| CVP                | Central Venous Pressure                               |
| DC                 | Direct Current  |
| DDoS               | Distributed Denial of Service                         |
| Des                | Desflurane  |
| Dia                | Diastolic   |
| DoS                | Denial of Service                                     |
| ECG                | Electrocardiogram                                     |
| EEC                | European Economic Community                           |
| EMC                | Electromagnetic Compatibility                         |
| EMI                | Electromagnetic Interference                          |
| Enf                | Enflurane   |
| ESU                | Electrosurgical Unit                                  |
| et                 | End-tidal   |
| etCO <sub>2</sub>  | End-tidal Carbon Dioxide                              |
| etN <sub>2</sub> O | End-tidal Nitrous Oxide                               |

|                    |  |
|--------------------|--|
| eto                | Ethylene Oxide                                   |
| etO <sub>2</sub>   | End-tidal Oxygen                                 |
| ExtremeTachy       | Extreme Tachycardia                              |
| ExtremeBrady       | Extreme Bradycardia                              |
| Fi                 | Fraction of Inspired                             |
| FiCO <sub>2</sub>  | Fraction of Inspired Carbon Dioxide              |
| FiN <sub>2</sub> O | Fraction of Inspired Nitrous Oxide               |
| FiO <sub>2</sub>   | Fraction of Inspired Oxygen                      |
| Hal                | Halothane  |
| Hb                 | Hemoglobin                                       |
| Hb-CO              | Carbon Mono-xide Hemoglobin                      |
| HR                 | Heart Rate                                       |
| IBP                | Invasive Blood Pressure                          |
| ICP                | Intracranial Pressure                            |
| ICU                | Intensive Care Unit                              |
| ID                 | Identification                                   |
| IEC                | International Electrotechnical Commission        |
| IEEE               | Institute of Electrical and Electronic Engineers |
| IPVC               | Inserted Premature Ventricular Contraction       |
| Irr Rhythm         | Irregular Rhythm                                 |
| Iso                | Isoflurane                                       |
| LA                 | Left Arm   |
| LAP                | Left Atrial Pressure                             |
| LCD                | Liquid Crystal Display                           |
| LED                | Light Emitting Diode                             |
| LL                 | Left Leg   |
| Low Voltage(Limb)  | Low QRS Voltage                                  |
| MAP                | Mean Arterial Pressure                           |
| MDD                | Medical Device Directive                         |
| MetHb              | Methemoglobin                                    |
| MRI                | Magnetic Resonance Imaging                       |
| Multiform PVCs     | Multiformed Premature Ventricular Contractions   |
| N/A                | Not Applied                                      |
| N <sub>2</sub>     | Nitrogen   |
| N <sub>2</sub> O   | Nitrous Oxide                                    |
| Neo                | Neonate  |
| NIBP               | Non-invasive Blood Pressure                      |
| Non-Sustain VT     | Nonsustained Ventricular Tachycardia             |
| O <sub>2</sub>     | Oxygen   |

|                  |   |
|------------------|---|
| oxyCRG           | Oxygen Cardio-respirogram                           |
| PA               | Pulmonary Artery                                    |
| PAC Bigeminy     | Premature Atrial Contraction (PAC) Bigeminy         |
| PAC Trigeminy    | Premature Atrial Contraction (PAC) Trigeminy        |
| PAWP             | Pulmonary Artery Wedge Pressure                     |
| Ped              | Pediatric   |
| Pleth            | Plethysmogram                                       |
| PPG              | Photoplethysmogram                                  |
| PR               | Pulse Rate  |
| PVC              | Premature Ventricular Contraction                   |
| PVC Bigeminy     | Premature Ventricular Contraction Bigeminy          |
| PVC Trigeminy    | Premature Ventricular Contraction Trigeminy         |
| R                | Right   |
| RA               | Right Arm   |
| RAP              | Right Atrial Pressure                               |
| Resp             | Respiration   |
| RHb              | Reduced Hemoglobin                                  |
| RL               | Right Leg   |
| RR               | Respiration Rate                                    |
| Run PVCs         | Run premature Ventricular Contractions              |
| Sev              | Sevoflurane   |
| SpO <sub>2</sub> | Functional oxygen saturation of arterial hemoglobin |
| Sustain VT       | Sustained Ventricular Tachycardia                   |
| SYS              | Systolic Pressure                                   |
| Tachy            | Tachycardia   |
| TB               | Blood Temperature                                   |
| TD               | Temperature Difference                              |
| TEMP             | Temperature   |
| USB              | Universal Serial Bus                                |
| VEB              | Ventricular Escape Beat                             |
| Vent Brady       | Ventricular Bradycardia                             |
| Vent Rhythm      | Ventricular Rhythm                                  |
| V-Fib/V-Tach     | Ventricular Fibrillation/Ventricular Tachycardia    |
| V-Tach           | Ventricular Tachycardia                             |
| Wide QRS Tachy   | Wide QRS Tachycardia                                |



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